EXPERT WORKSHOP

IMPACT OF TRADITIONAL CHINESE MEDICINE (TCM) ON PHARMACEUTICAL PRACTICES IN EUROPE

PROCEEDINGS

28 October 2010
European Directorate for the Quality of Medicines & HealthCare (EDQM)
7 Allée Kastner, CS 30026
F-67081 Strasbourg
## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>I – PROGRAMME</td>
<td>5</td>
</tr>
<tr>
<td>II – KEYNOTE ADDRESS</td>
<td>11</td>
</tr>
<tr>
<td>Professor Emilio MINELLI</td>
<td>13</td>
</tr>
<tr>
<td>The role of Traditional Chinese Medicines (TCM) in the European Environment</td>
<td>13</td>
</tr>
<tr>
<td>III – INTRODUCTION AND OVERVIEW</td>
<td>23</td>
</tr>
<tr>
<td>Dr Christian KALCHER</td>
<td>25</td>
</tr>
<tr>
<td>Activities of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate Committee of Experts CD-P-PH/PC dealing with quality and safety standards in pharmaceutical practices and pharmaceutical care</td>
<td>25</td>
</tr>
<tr>
<td>IV – ABSTRACTS AND PRESENTATIONS</td>
<td>29</td>
</tr>
<tr>
<td>Session theme: Impact of Traditional Chinese Medicine (TCM) in Europe</td>
<td>30</td>
</tr>
<tr>
<td>1.1 Medical-toxicological considerations</td>
<td>32</td>
</tr>
<tr>
<td>Professor Olavi PELKONEN</td>
<td>32</td>
</tr>
<tr>
<td>1.2 Considerations from the perspective of products used in TCM</td>
<td>39</td>
</tr>
<tr>
<td>Professor Dr Rudolf BAUER</td>
<td>39</td>
</tr>
<tr>
<td>Session theme: Legal framework of TCM in Europe</td>
<td>45</td>
</tr>
<tr>
<td>2.1 Legal framework of Traditional Chinese Medicine in Europe: Regulation in Switzerland</td>
<td>47</td>
</tr>
<tr>
<td>Dr Karoline MATHYS BADERTSCHER</td>
<td>47</td>
</tr>
<tr>
<td>2.2 Legal perspectives</td>
<td>52</td>
</tr>
<tr>
<td>Mr Markus AMBROSIUS</td>
<td>52</td>
</tr>
<tr>
<td>Session theme: Practice of TCM in Europe</td>
<td>55</td>
</tr>
<tr>
<td>3.1 Official training courses for professionals practicing Traditional Chinese Medicine (TCM)</td>
<td>57</td>
</tr>
<tr>
<td>Dr Yan MA</td>
<td>57</td>
</tr>
<tr>
<td>3.2 Perspectives on professional standards</td>
<td>65</td>
</tr>
<tr>
<td>Mr Albert L. De VOS</td>
<td>65</td>
</tr>
<tr>
<td>BREAK-OUT SESSIONS</td>
<td>67</td>
</tr>
<tr>
<td>BREAK OUT SESSION 1</td>
<td>68</td>
</tr>
<tr>
<td>A legal framework in Europe taking account of the specific approaches used in TCM</td>
<td>68</td>
</tr>
<tr>
<td>BREAK OUT SESSION 2:</td>
<td>70</td>
</tr>
<tr>
<td>TCM: Professional standards, practice and training courses</td>
<td>70</td>
</tr>
</tbody>
</table>
I – PROGRAMME

TCM is a comprehensive medical concept for the prevention and therapy of diseases based on pharmacological and non-pharmacological interventions such as the administration of medicines consisting of herbs or non-plant substances, nutrition, massage therapy (Tuina), and the self-cultivation approach “Qigong”.

There is growing demand for and promotion of foreign traditional medicine including TCM in Europe. There are specific risks associated with the use of TCM in a western environment by persons often unfamiliar with the underlying medical traditions.

The Committee of Experts on Quality and Safety Standards for Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) carried out in 2008/2009 a survey on the status of TCM in Europe:

- The results indicated that unlicensed medicines manufactured outside Europe often do not comply with international or European quality standards. Furthermore, the range of products used in TCM covers products classified in Europe as medicines, foodstuffs, food supplements, cosmetics and borderline products.

- There are major differences in Europe concerning the legal status of TCM and different regulatory approaches. There is a lack of harmonised requirements for the qualification, training and professional regulation of persons practising TCM: in some countries in Europe only medical doctors can legally practise TCM, whereas in other countries therapists and practitioners who are not medical doctors can do so.

- Overall, there is insufficient knowledge about the impact of TCM on pharmaceutical practices and public health in Europe.

- Public health in Europe will benefit from harmonised policies on the products and practices used in TCM practice, from balanced information for consumers and patients and from surveillance of the safety of TCM practices including the use of TCM products. Furthermore, a clear need was voiced for specific training for TCM-prescribers, dispensers, practitioners and therapists.

The CD-P-PH/PC programme of activities is aimed at the development of public health oriented policies and practices and at giving practical support for their implementation. These activities are co-ordinated by the Council of Europe European Directorate for the Quality of Medicines and HealthCare (EDQM), Department of Biological Standardisation, European Network of Official Medicines Control Laboratories & HealthCare (DBO).

The activities of the CD-P-PH/PC are complementary to the work carried out by the European Pharmacopoeia Commission on the preparation of pharmacopoeial monographs and general chapters related to herbal drugs used in TCM.
Aim of the expert workshop

Discussion and outline of

- a comprehensive strategy on how to obtain knowledge and spread awareness about the impact of TCM including the use of TCM products, specific training and education;

- options to inform patients and the general public about the benefits, limitations and risks of TCM in an appropriate and balanced way and to establish safety surveillance of TCM practices including the use of TCM products;

- key elements of a legal framework ensuring that TCM can be practiced safely without endangering public health, taking account of the needs of patients and practitioners as regards TCM.

Target audience

Participants with expertise and professional experience in quality assessment, clinical safety, market surveillance and pharmacovigilance matters related to TCM in Europe including representatives from:

- health or other authorities, such as the ministries of health, drug regulatory authorities, food & consumer protection and food & agriculture authorities, as appropriate,

- relevant professional associations in Europe, independent patient associations,

- international organisations and European institutions such as the European Commission, subordinate agencies and the WHO,

- delegations of bodies coordinated by the EDQM such as the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), steering body, and its subordinate committees of experts and the European Pharmacopoeia Commission including relevant working groups.

Working Methods

Plenary sessions and break-out sessions

The conference conclusions will be adopted at the end of the expert workshop by the participants.
Welcome address and opening

Chair:
9:00 a.m. Dr Susanne KEITEL, Director, EDQM

Keynote address

9:10 a.m. The role of Traditional Chinese Medicines (TCM) in the European environment
Speaker: Professor Emilio MINELLI, World Health Organisation Collaborating Centre for Traditional Medicine, Italy

Introduction and overview

9:30 a.m. Activities of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate Committee of Experts CD-P-PH/PC dealing with quality and safety standards in pharmaceutical practices and pharmaceutical care
Speaker: Dr Christian KALCHER, Vice-Chair of the Committee of Experts CD-P-PH/PC, Federal Ministry of Health, Austria

09:45–10:15 a.m. Coffee break

Chair: Dr Christian KALCHER

Session theme: Impact of Traditional Chinese Medicine (TCM) in Europe

10:15 a.m. Medical-toxicological considerations Speaker: Professor Olavi PELKONEN, Department of Pharmacology and Toxicology, Finland

10:35 a.m. Considerations from the perspective of products used in TCM Speaker: Professor Dr Rudolf BAUER, University Graz, Austria

Session theme: Legal framework of TCM in Europe

10:55 a.m. “Legal framework of Traditional Chinese Medicine in Europe: Regulation in Switzerland" Speaker: Dr Karoline MATHYS BADERTSCHER, Swissmedic, Swiss Agency for Therapeutic Products, Switzerland

11:15 a.m. “Legal perspectives" Mr Markus AMBROSIUS, Lawyer
Session theme: Practice of TCM in Europe

11:35 a.m. Official training courses for professionals practicing Traditional Chinese Medicine
Speakers: Dr Yan MA, Medical University Vienna, Austria

11:55 a.m. Perspectives on professional standards
Speakers: Mr Albert L. De VOS, ETCMA

12:30 –2:00 p.m. Lunch

Thursday, 28 October 2010

Break-out sessions (BS)

2:00–3:30 p.m.

Multidisciplinary groups of participants selected for the individual break-out sessions according to their expertise and preference will break out in parallel sessions (1-3). All break-out sessions will be attended by moderators and rapporteurs.

The participants will outline

• a comprehensive strategy for obtaining knowledge and increasing awareness about the impact of TCM in Europe, including specific training and education;
• options to inform patients and the general public appropriately about the benefits, limitations and risks of TCM and to establish safety surveillance of TCM practices;
• key elements of a legal framework ensuring that TCM can be practiced safely taking account of the needs of patients and practitioners.

At the beginning of each break-out session, the participants will agree on the working methods which will be used in the individual break-out session. The participants will be supplied with background reading and working documents before the expert workshop.

A legal framework in Europe taking account of the specific approaches used in TCM

Moderator: Dr Katrin JAHN, Swissmedic, Swiss Agency for Therapeutic Products, Switzerland
Rapporteur: Mr Markus AMBROSIUS, Lawyer

Room: Salle 100

TCM: Professional standards, practice and training courses

Moderator: Professor Dr Gertrude KUBIENA, Advisory Board TCM of the Federal Ministry of Health, Austria
Rapporteur: Dr Reinhard LÄNGER, AGES PharmMed, Austria

Room: Salle 400

Access for patients in Europe to reliable information on TCM

Moderator: Dr Karen PILKINGTON, University of Westminster, United Kingdom
Rapporteur: Mr Einar MAGNUSSON, Ministry of Health, Iceland

Room: Salle 600

3:30–4:00 p.m. Coffee break
### Session theme: Approaches to provisions for practices in TCM and practical assistance for implementation

#### Panel discussion – Conclusions

4:00–4:45 p.m.

*Moderator: Dr. Friederike ZECHMEISTER-MACHHART, Federal Ministry of Health, Austria*

The break-out session moderators will present the conclusions and moderate a discussion with the audience on the conclusions, the next steps for going forward, and in particular to establish provisions for Traditional Chinese Medicine practices as a concept including the use of TCM products and to assist member states in the implementation of these provisions through practical programmes and activities. The workshop conclusions will be adopted by the audience.

| 4:45 p.m. | Closing address | Speaker: Jean-Marc SPIESER |
II – KEYNOTE ADDRESS
**Professor Emilio MINELLI**  
*World Health Organisation Collaborating Centre for Traditional Medicine, Italy*

**The role of Traditional Chinese Medicines (TCM) in the European Environment**

**Introduction**

Traditional Chinese Medicine (TCM) is part of a more wide knowledge of the mankind that is the Traditional Medicine/Complementary and Alternative Medicine (TM/CAM). WHO defines TM/CAM as including different health practices, approaches, knowledge and beliefs; as incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination, to maintain well-being, as well as to treat, diagnose or prevent illness. In TCM there are different components like, for example, Acupuncture and Herbal Medicine, the most famous ones, but also Tuina, Qigong, Taijiquan and so on.

In general, WHO believes that TM/CAM should be considered and protected as resource for the health care and wellbeing of the mankind. In the document Strategy 2002-2005, WHO has identified a path for the implementation of the quality of TM/CAM. In general, more integration, more safety and efficacy and more rational use are believed necessary for reaching a high quality levels in the use of TM/CAM.

More, on 24 May 2008, in the Sixty-First World Health Assembly, WHO has defined the Global strategy and plan of action on public health, innovation and intellectual property.

In this document is strongly affirmed the need of promoting innovation based on TM/CAM within an evidence-based framework; of promoting standard setting to ensure quality, safety and efficacy of traditional medicine and to implement availability of public health libraries.

Indeed, TCM and Conventional Medicine (CM) are two medicines that spring from two different epistemological models. While the philosophy of CM is based on reductionism, the philosophy of TCM is based on a holistic view of the man and of the nature. While CM does quantitative evaluations of the biological phenomena of the body and of the mind, TCM prevalently does qualitative evaluations and distinctions. For these reasons, the final outcome of these two medical systems is often a description of the diseases and of the therapies that is incomprehensible for the doctors of the two different medical systems and for the consumers also.

For this reason, it's quite possible that:

1. **The same term not always means the same thing**
   For example, when we speak of Flaming-up of Liver-Fire, we don't speak of the liver described by western anatomy but of a psychological function.

2. **Different systems of collecting data produce different ways of diagnosis**
   It's quite evident that if we use different techniques to evaluate the symptoms of a disease we'll get different diagnosis. For example, if we observe the tongue or if we evaluate the amount of estrogens in the blood, we'll get a different classification of the menopause.

3. **Different criteria for diagnosis produce a different nosography**
   While the symptoms of a disease are almost the same for CM and TCM, the way in which these are collected in describing a disease may be very different. Of course, this difference is related to the different philosophical framework of the two medical systems, but the final pathological frameworks could be completely different. So we can see that not always there is a correspondence one to one between Western and Chinese nosographic descriptions and that if in CM we have one menopausal syndrome, in TCM we have several menopausal syndromes.
Information
For this reason, it’s quite evident that one of the main challenges for the development of TCM in Europe is the information.

Information that must involve consumers but also Medical doctors, Pharmacists, Herbalists, Mass-media and Internet.

Of course, the building of a high level of information system points out the problem of some specific interventions as, for example, the creation of a National policy and regulatory frameworks; the implementation of safety, efficacy and quality of practices and products of TCM; the attention to availability and to rational use of TCM.

A particular attention must be reserved to the use of Internet for self-medication. Great prudence must be recommended as suggested by WHO in the guidelines entitled Medical products and the Internet: a guide to finding reliable information.

Training
The increase of information between doctors and health care professionals requires programs of basic and advanced training. Indeed, for integrating WM and TCM it’s necessary that doctors learn either to know physiology and pathology along CM language, either to know physiology and pathology along TCM language.

The problem of the training has been faced by WHO with several publications as “Guidelines on basic training and safety in acupuncture” (1999); Benchmark for training on Tuina (2010) and Benchmark on Traditional Chinese Medicine (2010). Of course, a basic training system it’s not enough for obtaining a high level of information and of quality of the products and practices of TCM. Other activities that are useful are a system of continuous learning and a system of certification of the doctors and of the health care professionals.

In this activity of training the system of Universities could play a central role for the possibility of integration of the CM knowledge and of the TCM knowledge and for the possibility of doing research. For example, the State University of Milan holds from 1998: a Triennial Basic Course on Acupuncture, an Annual Advanced Course for Basic Chinese Dietetics and Pharmacology; an International Master of Integration between Chinese and Western Medicine. The intention of these courses is to teach to conventional medical doctors the use of TCM in some fields of the therapy for which there is evidence of efficacy in the international literature.

Continuous learning means also more refresher courses on TCM for TCM health care professionals and for conventional doctors and health care professionals also. This seems the only way for creating a communication between different health care categories.

Chinese herbal medicines (CHM): quality and safety
The Chinese herbs market it’s a very big and problematic matter. In 2005 sales revenue from traditional Chinese medicines totalled USD 14 billion and increased 23.81% compared to the last year. Exports of traditional Chinese medicines totalled USD 830 million and increased 14.55% compared to the same period last year. TCM market share: 30% of total sales of medicines. These data are useful for understanding that the Chinese herbs market has a fast growth also in Europe. Unfortunately, the quality of the Chinese products is not increasing with the same speed.

A deeper harmonisation of the laws and regulations of the EU countries related to the marketing of Chinese herbal medicines is desirable, but in any case the diffusion of more information is a system for protecting the consumers.
Either the consumer or the health care professionals when use a Chinese herbal medicines (CHM) should pay attention in considering it:

- The use is supported by clinical data.
- The use is supported by pharmacological data.
- The use is described in pharmacopeias and well established documents.
- The use is described in traditional medicine.
- The use is supported only by popular use.

The adverse reactions should be monitored and communicated to a net that includes authorities of pharmacovigilance but also pharmacists, conventional doctors and TCM health care professionals. An example of questionnaire that the consumers could use is presented.

In general, the creation of public websites can be useful for spreading information and for collecting data on the use of TM/CAM and of TCM also. In 2010 the our WHO CC in collaboration with the Regional Institute of Research of Lombardy (IReR) has created a website (www.medicomlombardia.it) that has the aim of implementing the communication between health care professionals, consumers and policy authorities. The website includes a database in which have been collected bibliographic references selected by a scientific board. While the website is more directed to consumers, the database is specifically dedicated to health care professionals.

Research

Of course, the integration of TCM and CM in European environment needs sound evidences that can be reached only through specific research programs. At the moment, the quality of research in the field of TCM is not very high and the number of the good quality studies is more and more increasing, but it is not still enough. The situation is very similar if we consider the CHM.

The main challenges for TCM Clinical Studies are classic and are related to the problem of placebo, to the control group and to the individualisation of the treatment. Indeed it’s very hard to make double blind studies on acupuncture and manual therapies because it’s very difficult to find placebo “points” or placebo “manual treatment”. Finally, the TCM operators expect success through individualisation, but the individualization of the treatments is obviously a great challenge to the statistic tools at the moment of the randomisation. The individualisation of treatment should be considered a strength of CAM rather than merely a research problem. If the need for individualisation is neglected in research design, the design will fail to apply the medicine as practiced and will fail to evaluate its potential benefit. Compromises may be made in order to make a trial of therapy possible but they may diminish therapeutic effect.

Another bias is related to the skills of the operators. The efficacy of most forms of non-medication of TM/CAM depends heavily upon the proficiency of the practitioners, including their skills, experience and received training. This may partly explain the disparity or inconsistency of results reported by different practitioners. This is a bias that it is difficult to measure or quantify.

A legal framework

Which contribution could be given by WHO for a deeper harmonization of the role of TCM in European health care systems? In WHO’s Agenda for the next five years there are six points and one of these brings into focus the health care systems.

The suggestions derived from WHA 62.13 Resolution on Traditional Medicine, May 2009 for integrating TM/CAM into health care systems, and TCM also, say that it’s very important:
- to formulate national policies and regulations for TM/CAM;
- to include traditional medicine service into health care systems and delivery;
- to establish qualifications and licensed practice and education/training program;
- to develop research and innovation of TM/CAM.
One menopausal syndrome or several menopausal syndromes?

- Liver and Kidney yin Deficiency
- Heart and Kidney Disharmony
- Spleen and Kidney yang Deficiency
- Kidney yin and yang Deficiency

More information for alls

For:
- Consumers
- Medical doctors
- Pharmacists
- Herbalists
- Mass-media
- Internet

Some challenges of TCM in Europe

- National policy and regulatory frameworks
- Official recognition of TCM practice and TCM operators
- Adequate allocation of resources for TCM development and capacity building
- Safety, efficacy and quality
- Research methodology and adequate evidence bases for TCM therapies and products
- Support for research
- International and national standards for ensuring safety, efficacy and quality control of TCM therapies and products
- Regulation and regulation of herbal medicines
- Access
- Need to identify safe and effective therapies and products for consumers
- Cooperation between TCM providers and conventional doctors
- Sustainable use of medicinal plants resources
- Rational use
- Training for TCM operators and on TCM for conventional doctors
- Communication between TCM and conventional practitioners, and between conventional practitioners and consumers

More information for consumers

- Summary of Key Points:
  - Privacy policy. By accessing and using the website, you agree to the use of cookies and similar technologies. If you do not agree to the use of cookies and similar technologies, please do not access and use the website.
  - The information provided here is not intended as a substitute for medical advice. Always consult your doctor or other healthcare provider about your specific medical condition and treatment.
  - Information that is not directly related to the treatment of your specific condition should be shared with your health care provider.
  - Although it offers TCM advice, this website provides a summary of relevant studies and research findings. It does not provide medical advice or treatment recommendations.
  - The content is intended to be educational and informative, but is not a substitute for professional medical advice. Always consult your doctor or other healthcare provider about your specific medical condition and treatment.
  - Information on the website is subject to change and may be updated periodically.
  - Only available online: For more information, please visit the website.

Training

- For integrating WM and TCM
- It's necessary that doctors learn
- Either:
  - To know physiology and pathology along Western Medicine Language
  - To know physiology and pathology along Traditional Chinese Medicine Language

Professor Emile MINELLI
The role of Traditional Chinese Medicines (TCM) in the European Environment
The role of Traditional Chinese Medicines (TCM) in the European Environment

More references courses on TCM for conventional doctors and health care professionals

Chinese herbs market

In 2005
- Sales revenue from traditional Chinese medicines totalled USD 14 billion and increased 23.81% compared to the last year.
- Exports of traditional Chinese medicines totalled USD 830 million and increased 14.55% compared to the same period last year.
- TCM market share: 30% of total sales of medicines

More information on herbal medicines (CHM)

Must be clearly pointed out if:
- The use is supported by clinical data
- The use is supported by pharmacological data
- The use is described in pharmacopoeias and well established documents
- The use is described in traditional medicine
- The use is supported only by popular use

Training

State University of Milan

1. Triennial Basic Course on Acupuncture
2. Annual Advanced Course for Basic Chinese Dietetics and Pharmacology
3. International Master of Integration between Chinese and Western Medicine
The role of Traditional Chinese Medicines (TCM) in the European Environment

More information: www.medicomlombardia.it

More information: www.medicomlombardia.it

Traditional Chinese Medicine

Conventional Medicine

E.M.

The challenges of the research in TCM

Poor quality of research

Systematic reviews of acupuncture for pain disorders

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Author, Year</th>
<th># Trials</th>
<th>Results</th>
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<tbody>
<tr>
<td>Chronic Pain</td>
<td>Paiol, 1989</td>
<td>14</td>
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</tr>
<tr>
<td></td>
<td>Ter Reit et al., 1990</td>
<td>51</td>
<td>Inconclusive</td>
</tr>
<tr>
<td></td>
<td>Ezio et al., 2008</td>
<td>51</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Low Back Pain</td>
<td>Ernst et al., 1989</td>
<td>12</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Furlan et al., 2005</td>
<td>35</td>
<td>Positive</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>Ernst, 1983</td>
<td>13</td>
<td>Inconclusive</td>
</tr>
<tr>
<td></td>
<td>Eeck et al., 2001</td>
<td>7</td>
<td>Positive/Inconclusive</td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td>Berman et al., 1999</td>
<td>7</td>
<td>Positive</td>
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Poor quality of research

Systematic reviews of Chinese herbal medicine

<table>
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<tr>
<th>Disorder</th>
<th>Author, Year</th>
<th># Trials</th>
<th>Results</th>
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<td>Armstrong et al., 1999</td>
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<td>Positive/Inconclusive</td>
</tr>
<tr>
<td></td>
<td>Hoare et al., 2001</td>
<td>277</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Asthma</td>
<td>Huntley et al., 2000</td>
<td>6</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Dementia</td>
<td>Jhong et al., 2004</td>
<td>66</td>
<td>Positive/Inconclusive</td>
</tr>
<tr>
<td>Type II Diabetes</td>
<td>Liu et al., 2004</td>
<td>66</td>
<td>Positive/Inconclusive</td>
</tr>
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Challenges for TM/CAM Clinical Studies

- Difficulty to make double blind: acupuncture and manual therapies
- Difficulty to make placebo "points" or placebo "manual treatment"
- TCM operators expect success through individualization of treatment.
Difficulties for TM/CAM Clinical Studies

- The efficacy of most forms of non-medicinal treatments in TCM/CAM depends heavily upon the proficiency of the practitioners, including their skills and experience even received training.
- This may partly explain the disparity or inconsistency of results reported by different practitioners.
- This is a bias that it is difficult to measure or quantify.

Six-Points in WHO’s Agenda for the Next 5 Years

1. Health and development
2. Health and security
3. Health systems
4. Information, knowledge
5. Partnerships
6. Performance

How to integrate TM/CAM into health system

According to WHO #22 Resolution on Traditional Medicine, May 1999

- Need to formulate national policies, regulations for TM/CAM
- Need to include traditional medicine service into health systems and delivery system
- Need to establish qualifications and licensed practice and education/training programmes
- Need to develop research and innovation of TM/CAM

Thank you !!!
III – INTRODUCTION AND OVERVIEW
Dr Christian KALCHER
Vice-Chair of the Committee of Experts CD-P-PH/PC, Federal Ministry of Health, Austria

Activities of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate Committee of Experts CD-P-PH/PC dealing with quality and safety standards in pharmaceutical practices and pharmaceutical care

The activities in the field of pharmaceutical questions in the framework of the Council of Europe have a very long history and go back into the early fifties of the last century. Until 2007 the “Committee of Experts on Pharmaceutical Questions” existed in the Partial Agreement in the Social and Public Health field of the Council of Europe. This Committee developed several Resolutions, adopted by the Committee of Ministers, dealing with the challenges of pharmacists and of consumer protection in the context of medicines and public health; equally seminars on these topics have been organised.

These activities have been moved in 2008 to the EDQM (European Directorate for the Quality of Medicines and Health Care) that has been created on the basis of the Convention on the Elaboration of a European Pharmacopeia. A Steering Body (European Committee on Pharmaceuticals and Pharmaceutical Care) and three subordinate Committees have been set up in order to build on what has been achieved in the decades before in this field. One of the three subordinate Committees is the “Committee of Experts CD-P-PH/PC dealing with quality and safety standards in pharmaceutical practices and pharmaceutical care. This Committee is currently engaged in three major projects: TCM, “Pharmaceutical Care” and “Pharmacy Preparations”. Workshops have been organised on these subjects and a draft “Resolution on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients” has already passed the Steering Committee and it is planned to submit it this fall to the Committee of Ministers for adoption.

The Terms of Reference of this Committee are the basis for it’s’ activities. In the Terms of Reference the objectives of the Committee are stated as follows:

“develop and carry out a programme of activities aiming at improving public health care in Europe through promoting knowledge, skills, attitudes and values in practices and care involving pharmaceuticals, in particular (inter alia):

Relevant non-European traditional therapies used in Europe

The Committee decided to start in this field with a project on “Traditional Chinese Medicine” (TCM), due to its increasing relevance in many European countries. A small working group was established and as a first step it developed a questionnaire that was circulated to all Member States of the European Pharmacopoeia Convention. The evaluation of the answers showed there is no common strategy within Europe to tackle the specific problems in this field. Therefore, as a stock taking exercise, it was decided to give an overview of the various aspects of TCM written by experts in the respective areas.

In the booklet “Impact of Traditional Chinese Medicine on pharmaceutical practice in Europe– Facts and Expert Opinions” the crucial issues and problems in this field are addressed.

The current workshop is planned as an opportunity to discuss the most important topics of the subject like legal framework, training, education and reliable information with experts coming from different European countries and to come to conclusions that can be the basis for a common understanding of the specific problems in this field. Eventually this should lead to a guidance document that reflects the best practice on TCM for the benefit of patients and consumers which is also in the interest of public health.
Activities of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate Committee of Experts CD-P-PH/PC dealing with quality and safety standards in pharmaceutical practices and pharmaceutical care.

History (until 2007)
Partial Agreement in the Social and Public Health field (Council of Europe)
Committee of Experts on Pharmaceutical Questions

Current Structure (since 2008)
EDQM (European Directorate for the Quality of Medicines and Health Care)
- European Committee on Pharmaceuticals and Pharmaceutical Care (Steering Body)
- 3 subordinate Committees

Current Structure
- Committee of Experts on the classification of medicines as regards their supply
- Committee of Experts on minimising public health risks posed by counterfeiting of medicinal products and related crimes
- Committee of Experts on quality and safety standards in pharmaceutical practices and pharmaceutical care

Terms of Reference
„Develop and carry out a programme of activities aiming at improving public health care in Europe through promoting knowledge, skills, attitudes and values in practices and care involving pharmaceuticals“

Projects
- Pharmaceutical Care
- Pharmacy preparations
- Traditional Chinese Medicine (TCM)
Proceedings of Traditional Chinese Medicine (TCM) Expert Workshop, 28 October, Strasbourg

Dr. Christian KALCHER
Activities of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate Committee of Experts CD-P-PH/PC dealing with quality and safety standards in pharmaceutical practices and pharmaceutical care.

**Pharmaceutical Care**
- Concepts, quality assessment in Europe, sources of information (survey report 2009)
- Development of Pharmaceutical Care indicators
- Implementation of action plan

**Pharmacy preparations**
Draft „Resolution on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients“

**Traditional Chinese Medicine**
- Questionnaire
- Evaluation of answers
- Booklet „Impact of Traditional Chinese Medicine on pharmaceutical Practice in Europe – Facts and Expert Opinions“

**TCM Workshop**
- Legal framework
- Quality standards
- Training and education
- Reliable information

**TCM Workshop**
Aim of the Workshop:
A guidance document that reflects the best practice on TCM in Europe
IV – ABSTRACTS AND PRESENTATIONS
Session theme: Impact of Traditional Chinese Medicine (TCM) in Europe
Session Chair:

Dr Christian KALCHER  
Vice-Chair of the Committee of Experts CD-P-PH/PC, Federal Ministry of Health, Austria

Speakers:

Professor Olavi PELKONEN  
Department of Pharmacology and Toxicology, Finland

Professor Dr Rudolf BAUER  
University Graz, Austria
The attitude of the medical establishment in Europe, especially in Scandinavia, towards TCM varies from lukewarm tolerance or interest to outright rejection. There are seemingly irreconcilable differences between the conceptual frameworks of TCM and ‘Western’ medicine. In the opinion of medical community, scientific evidence for quality, efficacy and safety of TCM are incomplete, often of poor quality or totally lacking and there are probably no TCM which would fulfill the current requirements of ordinary drugs in Europe.

Although in China, and increasingly also in Europe, USA and other countries, scientific techniques and approaches are applied for the study of TCM, it seems likely that for many years we will not have a solid research basis for the use of TCM in Europe, which would be acceptable for both ‘Western’ medical practice and TCM. Admittedly, the most modern ‘omics’ and other techniques are applied for the study of TCM, but such research is slow and costly and the outcome is unpredictable. However, scientific research is necessary for better understanding of the subject, whatever the final outcome.

Committee of Herbal Medicinal Products (HMPC/EMA) is responsible for the assessment of quality, efficacy and safety of herbal medicinal products in EU and TCM products would fall under its sphere, at least to the extent that they are plant extracts and their combinations. [One should remember that also EFSA deals with botanical supplements and assess health effect claims, if any suggested.] However, currently there are no TCMs assessed by HMPC and it is difficult to say whether and to what extent the TCM would fulfill the formal requirements of well-established or traditional herbal medicinal products. Current EU legislation and its interpretation speak about ‘European experience’ and ‘European tradition’. If TCM were assessed by HMPC or a corresponding EU body, one of the first difficulties to be resolved would be the acceptability of evidence arising from a different tradition.

From the medical, pharmacological and toxicological points of view, the most important problems concerning TCMs in EU include the following: regulatory status (medicine or food); scientific evidence (quality, who should assess it?); acceptability of local, i.e. Chinese, data for quality, efficacy and safety; what are the minimum safety requirements etc. Bearing in mind the experiences of HMPC in the assessment of herbal medicinal products of ‘European tradition’, I do not see any quick, easy and mutually acceptable ways to TCM in Europe. Assessment takes time whatever the system. Building a solid research base takes even more time, but it is necessary to the acceptance by the medical and scientific communities.
Proceedings of Traditional Chinese Medicine (TCM) Expert Workshop, 28 October, Strasbourg

Professor Olavi PELKONEN
Medical-toxicological considerations

TCM in Europe: Medical-toxicological considerations
Olavi PELKONEN
Department of Pharmacology and Toxicology, University of Oulu, Finland

Alternative therapies or Complementary therapies
- Folk Medicines
- Herbal Medicines
- Chinese Herbal Medicines
- Ayurvedic medicines
- Megavitamins
- Functional foods
  - Probiotics
  - Prebiotics
- Homeopathic preparations
- Antiseptic preparations

Complementary medicines - What are the issues we should focus on?
- Are they foods or food supplements?
- Are they therapeutic agents?
- Should they be classified as drugs?
- If so, what issues should be considered?
  - Safety
  - Efficacy
  - Interaction potential
- How should they be regulated?
- How are they being regulated?

Regulatory positions
- Western “modern” positions
  - USA: dietary supplements
  - EU: medical products
  - Australia: somewhere between
- Chinese Traditional Medicine
- Ayurvedic medicine

Goals of Regulation of Herbal Medicinal Products in the European Union
- Harmonisation of requirements on quality, safety and efficacy for herbal medicinal products
- Improvement of pharmacovigilance for herbal medicinal products
- Facilitation of free movement of safe herbal medicinal products within the European Union

Are herbal medicinal products drugs in EU?
- According to Community legislation:
  - Yes, they are legally, but...
- They are in a special status in terms of testing requirements.
- Test and trial results can be replaced by appropriate scientific literature
- Which kind of scientific literature?
Safety and Efficacy

New products – New Tests and Trials

- Directive 2001/83/EC, Article 8
- ... 3. The application shall be accompanied by the following particulars and documents, submitted in accordance with Annex I: ...
- (...) Results of:
  - pharmacological (physico-chemical, biological or microbiological) tests,
  - pre-clinical (toxicological and pharmacological) tests,
  - clinical trials.

Marketing Authorization (bibliographic)

- 2001/83/EC as amended by CD 2004/27/EC
- Article 10a
- ... By way of derogation from Article 6(3)(a), the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognized efficacy and an acceptable level of safety in terms of the conditions set out in the Annex.

Assessment report and Community herbal monograph: Sources

- ESCOP Monographs (European Scientific Cooperative on Phytotherapy)
- WHO Monographs
- European Pharmacopoeias
- Other Pharmacopoeias
- Any Published Literature
- other information available to national competent authorities, e.g. pharmacovigilance data, studies etc.

HMPC Guidelines concerning Safety & Efficacy

- Guideline on non-clinical documentation for well-established and traditional herbal medicinal products
- Guideline on assessment of clinical safety and efficacy for well-established and traditional herbal medicinal products
- Guideline on clinical assessment of fixed combinations of herbal substances / herbal preparations
- Community Herbal Monographs and lists

Efficacy considerations

- Well-established herbal medicinal products: a single good clinical trial and supporting evidence (including >10 yr use in Europe)
- Traditional herbal medicinal products: indication supported by extended continuous use (>30 yr)
- Indications for WEU are more “drug-like” than indications for TUs

Non-clinical testing of herbal medicinal preparations with long-term experience

- Comprehensiveness and quality of evidence
- Tests not required, if sufficient experience in humans is available:
  - single dose toxicity,
  - repeated dose toxicity,
  - immunotoxicity
  - local tolerance testing
  - pharmacological tests including safety pharmacology
  - pharmacokinetic studies.
### Safety concerns of "old" substances
- Old substances are widely used, but there are few formal toxicological studies.
- Very little incentives to make such studies; no protection of data and intellectual property.
- Animal experiments are difficult to justify, if only the "completeness of dossier" is the goal.
- What is the value of past experience?

### Possible solutions to safety concerns of "old" substances
- Require formal studies (as pharmaceuticals; check-box approach).
- Accept common experience/"pharmacovigilance" data for safety assessment if no serious concerns.
- Mixed approach depending on a substance/preparation and specific toxicity.
- What creates "cause for concern"?

### Pharmacovigilance/Safety - examples
- Soy or peanut protein
- Capsaicum / capsaicin
- Chamomilla
- Aristolochia species
- Estragole
- Methylxugenol
- Pulegone and menthofuran
- Asafoetida
- Black cohosh

### St. John's wort (hypericum)
- Antidepressant
- E.g. hyperforin
- Safety - problems of interactions with drugs.
- Induction of CYP enzymes and some transporters → decrease in drug concentrations and efficacy.

### Problem issues in safety assessment of "old" substances
- Long-term use = Safety
- Certain forms of toxicity not easily recognizable in daily use or via pharmacovigilance.
  - Genotoxicity/mutagenicity
  - Carcinogenicity
  - Reproductive toxicity
- Potential interactions with pharmaceuticals.

### Consideration in toxicity testing of herbals
- Variable and often unknown composition of products.
  - Seasonal and geographical variations
  - Plant varieties
  - Unknown active ingredients
  - Identification may also be uncertain
  - Manufacturing and storage variations
- Variable formulations and dosage recommendations.
Safety problems in genotoxicity and mutagenicity
- A long lag period to detect the outcome (if any and if at all)
  - Germ cells – generations
  - Somatic cells – decades (carcinogenicity)
  - Embryo cells – next generation
- Exposure to multiple chemicals

Mutagenicity/Genotoxicity testing of herbal medicinal products
- The "full set" of ICH/OECD genotoxicity tests versus a reduced set of selected tests?
- What is the absolute minimum for acceptance of a registration/marketing authorisation of old herbal substances?
- No agency is asking for a full genotoxicity testing programme

Guideline on the assessment of genotoxic constituents in herbal substances/preparations
- A step-wise procedure
  - A bacterial reverse mutation test (Ames)
  - Mouse lymphoma cell assay
  - In vivo studies (mouse micronucleus test)
- Risk assessment problematic
  - ALARA, MOE, Uncertainty factors, TTC

Special consideration in genotoxicity testing of herbas
- Known genotoxicants in trace amounts
- Complex mixtures
- Variable composition
- Unspecific effects on bacteria or cells
- Differences between preparation and internal exposure
- Extrapolation from one preparation to another (generalization)

Some unanswered questions with traditional Chinese medicines
- Do we need the regulation of TCM?
- Do TCMs need a drug status in EU?
- Is HMPC a right forum for assessment?
- Evidence?
  - Science vs tradition?
  - Chinese literature?
  - Assessors? Who is competent?
- What is the role of current and future research
  - Advertisement?
- Role of scientific and medical community?
Angelica archangelica

- resistance to bacterial infection (trad.)
- efficacy – no evidence
- safety – furocoumarins
- interactions – no data

**Problems with risk assessment of Angelica archangelica**

- Furocoumarins – phototoxic, photogenotoxic, photocarcinogenic
  - carcinogenicity 8-MOP class 1 (IARC)
  - PI/VA therapy (30 mg/dose × 200 doses)
- Dietary exposure (celery etc.)
  - average 1.45 mg/day, up to 14-15 mg/day
- Exposure via diet and herbal preparation
  - matrix effects
  - difference in exposure pattern

**Safety problems in carcinogenicity**

- A long lag period to detect the outcome (if any)
  - Usually 20-40 years
  - Several mechanisms of action (genotoxicity is only one albeit an important one)
  - Requires multiple “hits”
- Exposure to multiple chemicals
- Testing

**Carcinogenicity testing**

- In vivo carcinogenicity tests (24-month rat study, 18-month mouse study)
- TG or KO strains (short-term tests)
- Colony forming assays (transformation assays)
- Gap junction inhibition assays

**Carcinogenicity – some considerations (4.4.)**

- Is the suspicion based on results of genotoxicity studies and can it be clarified in further genotoxicity studies, namely in vivo?
- Is the suspicion based on a possible epigenetic mechanism?
- Are the extent and the quality of the available scientific data (non-clinical, clinical, epidemiological, post-marketing etc.) sufficient to refute the suspicion taking into account the intended use?
- Are the extent and the quality of the available scientific data (non-clinical, clinical, epidemiological, post-marketing etc.) sufficient to come to a positive benefit-risk assessment and also factoring in the expected benefit from the herbal medicinal product?
Safety problems in reproductive toxicity

- Teratogenicity - the outcome manifests after birth or later
  - Different sensitivity of the target
  - Constantly changing target
  - Damage often irreversible
- Fertility – infertility difficult to detect
- Testing

Teratogenicity and fertility testing

- Teratogenicity tests (rodent, non-rodent)
- 3-generation reproductive toxicity test
- Perinatal toxicity test
- Developmental neurotoxicity test
- Behavioural teratogenicity test

Toxicity to Reproduction

- 4.2. Reproductive toxicological tests in animals are not necessary if one of the following criteria is fulfilled:
  - Results from post-marketing studies or epidemiological data of adequate power or post-marketing safety studies are available.
  - The assessment of the results of a systematic and comprehensive scientific literature search and post-marketing experience does not identify a positive signal of reproductive toxicity and the herbal medicinal product is not intended to be used during pregnancy and lactation.
  - Results from investigations in pregnant women and neonates are present.
  - The medicinal product is not intended to be used in women of childbearing potential.
1.2 Considerations from the perspective of products used in TCM

Professor Dr Rudolf BAUER

TCM Research Center Graz, Institute of Pharmaceutical Sciences
Karl-Franzens-University Graz, Austria

Traditional Chinese medicine has thousands of years of experience and is based on a specific theory with a holistic approach for disease and health management. In Europe, Chinese herbs are either used medicinally in the classical way in decoctions, or as extracts in herbal medicinal products. The safe use is based on a consistent and reliable quality.

Since Chinese herbs are still not very well known in Europe, they may be mixed up with toxic herbs if authentication is not performed properly. Similar Chinese names may lead to confusion and adulterations, like it was the case with *Stephania tetrandra* and *Aristolochia fangji*, which are named Han Fangji and Guang Fangji in Chinese. Similar mix-up has happened with Guan Mutong (*Aristolochia manshuriensis*), Chuan Mutong (*Clematis armandii*) or San Ye Mutong (*Akebia trifoliata*). Since aristolochic acid is toxic to liver and kidneys, a series of corresponding intoxications have been observed. For the same reason Madouling (*Aristolochia debilis* fruit), Qingmuxiang (A. debilis root), and Xungufeng (*Aristolochia mollissima*) should not be used. Aristolochic acid can be easily detected by TLC or HPLC.

A clear botanical definition and testing of the accepted plant species guarantees that related toxic species are not used. Therefore, monographs of Chinese herbs are currently elaborated for the European Pharmacopoeia.

Several Chinese herbs, like aconite (Radix Aconiti (Chuanwu), Radix Aconiti lateralis (Nifuzi), Radix Aconiti kusnezoffii (Caowu)), need to be processed before use in order to degrade toxic constituents. Unprocessed aconite roots are very toxic due to diterpene ester alkaloids, mesaconitine, aconitine and hyponaconitine. Processing reduces toxicity by hydrolysis of the toxic alkaloids. Another example is Fructus Xanthii, Cangerzi, which contains carboxylatroctyside, a highly selective inhibitor of cytosolic side-specific mitochondrial ADP/ATP carrier and toxic compound. Stir frying removes the compound and guarantees a safe use. Therefore, it is necessary to test in these cases by HPLC, whether processing has been performed properly.

Some Chinese herbs, like *Ligularia dentata* (Chiyetuowu); *Lithospermum erythrorhizon* (Zicao), or *Senecio scandens* (Qianliguang) are known to contain pyrrolizidine alkaloids. Pyrrolizidine alkaloids are highly liver toxic, and therefore limits and a test in the European Pharmacopoeia are urgently needed. Some risk may also occur from contamination with heavy metals, pesticides, mycotoxins and microbes. However, the European Pharmacopoeia has set limits and guarantees a safe use of herbs as medicinal products.

Finally, admixtures of highly potent pharmaceutical substances to finished products may cause risks, since consumers expect to take safe herbal drugs. Adding for example sildenafil without labelling represents a serious risk for patients with cardiac problems.

In summary, the use of Chinese herbal medicinal products is safe as long as they are produced and distributed under controlled conditions, and as long as serious quality control according to pharmacopoeia is involved. Uncontrolled use, however, bears the risk of adulterations, contaminations and intoxications.
Proceedings of Traditional Chinese Medicine (TCM) Expert Workshop, 28 October, Strasbourg

Expert workshop

Impact of Traditional Chinese Medicine in Europe: Considerations from the perspective of products used in TCM
Rudolf Bauer
Institute of Pharmaceutical Sciences
TCM Research Center Graz
Karl-Franzens-University Graz

Quality issues which seriously affect the safety of Chinese herbs
- Adulteration / mix-up with toxic herbs
- Constituents considered to be toxic
- Insufficient processing
- Contamination with heavy metals and pesticides
- Microbial load and mycotoxins
- Admixture of highly potent pharmaceutical substances

Missing harmonization of nomenclature is a challenge for authentication

HPLC Fingerprint Analysis of Angelica pubescens radix (Duhuo 独活) and Adulterants

Adulteration and Substitution
Han Fangji
Aristolochia manshuriensis radix
Stephanandra chinensis KAPOOR
Xinneyrini

Other Chinese herbs containing aristolochic acid:
- Guanmuoting (Aristolochia manshuriensis stem)
- Malouling (Aristolochia debils fruit)
- Qingmuxiang (Aristolochia debils root)
- Xingguoteng (Aristolochia mollissima)

More than 100 kidney interventions in Belgium (Aristolochia nephropathy)
More than 40 women now depend on dialysis
Several cases of kidney cancer

40
Proceedings of Traditional Chinese Medicine (TCM) Expert Workshop, 28 October, Strasbourg

**Considerations from the perspective of products used in TCM**

**Aconite roots in TCM**

*Radix Aconiti (Chuanwu)*

*Radix Aconiti lateralis (Nifuzi)*

*Radix Aconiti kusnezoffii (Caowu)*

**Pattern of alkaloids in unprocessed roots of Aconitum carmichaeli**

**The effect of processing on the alkaloid composition of roots of Aconitum carmichaeli**

**Content of toxic alkaloids in commercial aconite roots**

<table>
<thead>
<tr>
<th>Alkaloid</th>
<th>Content (mg/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aconitine</td>
<td>0.285</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.207</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.122</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.078</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.045</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.024</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.011</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.003</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.002</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.001</td>
</tr>
<tr>
<td>Aconitine</td>
<td>0.000</td>
</tr>
</tbody>
</table>

**The toxicity of Fructus Xanthii, Cangzhi 茜耳子**

*Carbohydrate-based toxicology of Fructus Xanthii, a traditional Chinese herbal medicine.*

*Jingles positioned by 3D printing followed by grinding to remove prickers.*
Chinese herbs with mandatory processing

<table>
<thead>
<tr>
<th>Herb</th>
<th>Latin Name</th>
<th>Chinese Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>BuGU Zhì</td>
<td>Fructus Psoraleae</td>
<td>YanChao</td>
</tr>
<tr>
<td>GuZHONG</td>
<td>Cortex Eucommiae</td>
<td>YanChao</td>
</tr>
<tr>
<td>SuANZHAO</td>
<td>Semen Ziziphi spinosae</td>
<td>Chao</td>
</tr>
<tr>
<td>HUOMAREN</td>
<td>Semen Cannabis</td>
<td>Chao</td>
</tr>
<tr>
<td>BAJITAN</td>
<td>Radix Morinae</td>
<td>Zhi</td>
</tr>
<tr>
<td>ROUSONGRONG</td>
<td>Herba Cistanches</td>
<td>Jiuzhi</td>
</tr>
<tr>
<td>HUANGJI</td>
<td>Rhizoma Polygonati</td>
<td>Jiuzhi</td>
</tr>
<tr>
<td>WANGBULIXING</td>
<td>Semen Vaccarii</td>
<td>PaChao</td>
</tr>
<tr>
<td>ROUDOUKOU</td>
<td>Semen Myristicae</td>
<td>Wei</td>
</tr>
</tbody>
</table>

Public consultation: Proposals to prohibit the sale, supply or importation of allium rice medicinal products for internal use which contain Senecio species and proposals to amend three existing orders.

Qianbii Biyan Plan Ph.PRC
- Herba Senecionis scandens 2424 g
- Herba Galpiniae 404 g
- Rhizoma et Radix Notopogonii 16 g
- Semen Cassiae 242 g
- Herba Eupatorium 81 g
- Rhizoma Chuanxiong 8 g
- Rhizoma Angelicae dahuricae 8 g

Pyrrolizidine alkaloids are a threat to human health and safety

- International Programme on Chemical Safety (IPCS), 1996

In 1992, the Federal Health Department of Germany has restricted the manufacture and use of pharmaceuticals containing pyrrolizidine alkaloids with a unbranched amino skeleton. The herbal plants may be sold and used only if daily external exposure to no more than 100 μg pyrrolizidine alkaloids and internal exposure to no more than 1 μg per day for no more than six weeks a year.

Sources of pyrrolizidine alkaloids
- Compositae family: In plants of the Senecionae subtribe (24 genera, the genus Senecio is prevalent), and the Eupatorine subtribe (mainly in the genus Eupatorium and Apaereta)
- Boraginaceae family: in virtually all plants of this family, and
- Fabaceae family (Leguminosae): in the subtribe Christonieae. Mainly in the genus Christonieae, but also in the genera Chromolaena and Loefloria.


Identification of five hepatotoxic pyrrolizidine alkaloids in a commonly used traditional Chinese medicinal herb, Herba Senecionis scandens (O. Kuntze).
The case of Zicao

- Obtained from Lithospermum erythrorhizon (Zicao 萃草) and Arnebia euchroma (Ruan Ziao 蒿 redistributed by the Boraginaceae family
- Total PA yield of Lithospermum erythrorhizon is ca. 0.017%, consisting mainly of intermetrine, and mycosporine
- Arnebia euchroma the total PA yield is only 0.0036%, comprised mainly of aragatoxytronecina
- What about Onosma purpureum (Tian Ziao 天紫草)?
- What about Zicao Gao (萃草膏)?

Contaminants in medicinal herbs: Heavy metals

- Limits for Herbal Drugs in Ph. Eur. 7.0
  - Lead max. 5.0 ppm
  - Cadmium max. 0.01 ppm
  - Mercury max. 0.005 ppm

Contaminants in medicinal herbs: Heavy metals

Mandatory tests for heavy metals in the Chinese Pharmacopoeia 2005:
- Panax quinquefolii Radix (Xi Yang Shen)
- Paeoniae Radix Alba (Bai Shao)
- Glycyrrhizae Radix (Gan Cao)
- Salviae Radix (Dan Shen)
- Lonicera Flos (Jin Yin Hua)
- Astragali Radix (Huang Qi)

Limbs: Lead 5.0 ppm, Cadmium 0.2 ppm, Mercury 0.01 ppm, Arsenic 2.0 ppm, Copper 20.0 ppm

Harmonization is needed!

Contaminations with pesticides

- General limits set by the European Pharmacopoeia (2.6.13. Pesticide residues)

Samples over limits:
- Carthami fol. HCH isomers (10x limit) Lindan
- Ginseng radix HCH isomers, hexachlorobenzene, quinoline and pentachloronitrobenzene hexachlorobenzene (10x limit)
- Inulae folis Angelicae sinensis Rad. HCH isomers
- Astragalus radix HCH isomers
- Citri retic. peric. Dioscol (35x limit)
- Semen flos Lonicera HCH isomers

Microbial contaminations

Limits set by the European Pharmacopoeia:
1.6.4. Microbiological quality of pharmaceutical preparations and substances for pharmaceutical use

2.8.31. Microbiological examination of herbal medicinal products for oral use

Observed contaminations (e.g.):
- Citri reticulatae viridissima pericarpium (Qingpi): too much fungi
- Crataegi fructus (Shanzha): too much fungi
- Farfarae flos (Kuandonghua): too much fungi
- Semen saponis (Fangxiao): too much fungi
- Semen flos (Tianma): enterobacteria
Proceedings of Traditional Chinese Medicine (TCM) Expert Workshop, 28 October, Strasbourg

Professor Dr. Rudolf BAUER
Considerations from the perspective of products used in TCM

Mycotoxins

- Toxic secondary metabolites of moulds
- Aflatoxins: Germany: VerboteV 16.7.2000:
  - max. 0.05 µg/kg Aflatoxin M1
  - max. 4 µg/kg Aflatoxin B1 (Ph.Eur. 2.0.10)
- Ochratoxin A (Ph. Eur. 2.0.22): European regulation EU-RL 2002/657EO for food (cereals, coffee, wine and grape (juice)): < 5 µg/kg body weight/day
- Patulin: European regulation EG 1425/2003 for food (apple products): 50 µg/kg

The "100 % natural" Herba Gra

Ingredients: Cladium monieri, Eupatorium macranthum, Dioscorea bulbifera, Astragalus membranaceus, Poria (Porphyria cocos, Rehmanniae glutinosae, and Radix Salviae miltiorrhizae, etc.

"etc." = ca. 35 mg Sildenafil !!!!

Press release: Serious health risk posed by Traditional Chinese Medicine Herbal Viagra

Press release: 07 Apr 2009

Wuchzhang - 50% Furocoumarin - 12%
Glehnia Louisii - 9%
Herba Ephedrae - 10%
Chinese Ginseng - 10%
P. Long. - 1%
Rh. Glu. - 1%

„The Jia Yi Jian product tested contained 68.1mg of Siloustramine and 50.01mg of Tadalafil."

Elaboration of Monographs for TCM herbs for the European Pharmacopoeia

- TCM-Working Party established
- 81 Monographs on the workshop
- 7 Monographs adopted by the Eur. Pharmacopoeia Commission
- Ca. 45 attributed to Specialists
- 12 Monographs published as drafts in PHARMEUROPA
- Monographs for General Methods:
  - Chapter on Processing: published
  - Test for Aristolochic acids: published
  - Test for Pyrrolizidine Alkaloids: pending

Conclusions

- In order to guarantee safety (and efficacy) of Chinese herbs, quality control is mandatory
- Mix-up and adulteration with toxic herbs must be prevented
- Processing of toxic herbs needs to be strictly controlled and end-points need to be defined
- Contamination with heavy metals and pesticides, as well as microbial load and mycotoxins must be tested
- Admixture of synthetic pharmaceutical substances must be ruled out
- European Pharmacopoeia plays an essential role in the safety concept of herbal medicinal products
Session theme: Legal framework of TCM in Europe
Session Chair:

Dr Christian KALCHER
Vice-Chair of the Committee of Experts CD-P-PH/PC, Federal Ministry of Health, Austria

Speakers:

Dr Karoline MATHYS BADERTSCHER
Swissmedic, Swiss Agency for Therapeutic Products, Switzerland

Mr Markus AMBROSIEUS
Lawyer, Germany
2.1 Legal framework of Traditional Chinese Medicine in Europe: Regulation in Switzerland

Dr Karoline MATHYS BADERTSCHER
Swissmedic, Swiss Agency for Therapeutic Products, Switzerland

In Switzerland TCM products are used by a raising number of medical doctors and therapists trained in TCM since more than twenty years. The Swiss Federal Act on Therapeutic Products (TPA\(^1\)), in force since January 2002, states that ready-to-use medicinal products may only be placed on the market if authorized by Swissmedic. Therefore, even traditional Chinese medicines (TCM) not sold under a specific product name (brand) and without medicinal claims on the label are considered to be ready-to-use medicines if sold to a person without manufacturing license, e.g. a medical doctor or a therapist, and require an authorization by Swissmedic.

An experts group comprising representatives of medical doctors trained in TCM, TCM therapists and experts in quality and GMP, concluded that the existing regulations for medicinal products may not be applicable to most of these products. This mainly because the products were not used for one clearly defined indication but always in changing, individual combinations to treat different illnesses. Even if based on a standard combination single-substance TCM are often added to optimize the individual therapy.

Traditional Chinese Medicines can be authorized in Switzerland according to the requirements defined in the Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products (OAMédcophy\(^2\)), in force since 22nd October 2006.

For TCM products with indication/therapeutic claims the requirements for (traditional) western herbal medicinal products apply, including the documentation on quality, safety and efficacy (see Arts. 5–7 and Art. 25 OAMédcophy). The combination must be justified according to TCM. Bibliographical documentation may be submitted as long as sufficient proof is available in published literature and the knowledge can be transposed to the medicinal product submitted.

For Medicinal products without indication/therapeutic claims labelled, a very simplified procedure and even a notification procedure can apply, as long as they fulfil clearly defined criteria (Art. 26 and 27 OAMédcophy). These criteria mainly include aspects like manufacturing according to international accepted GMP rules; only ingredients used in TCM for several decades and described in official pharmacopoeias or in recognized reference books, quoted in a list of traditional Asian substances (TAS list) published by Swissmedic; sufficient relevant literature available in an official language of Switzerland (German, French, Italian) or in English to guarantee the safe and appropriate use of the products by specialists qualified in TCM; oral or external application only; documented quality; no therapeutic indications on the labelling but declaration of the ingredients according to provisions given by Swissmedic. The requirements for the labelling (technical name) are specified in Annex 1b of the AMZV / OEMéd\(^3\). The responsibility for the choice of the correct TCM products and the safe and effective dosage of these products without indication, together with the corresponding prescription or recommendation, is under the responsibility of the TCM-trained medical doctor or the TCM therapist.

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\(^1\) SR 812.21
\(^2\) SR 812.212.24
\(^3\) SR 812.212.22
For fixed combinations of traditional Chinese medicines without indications, it is also possible to omit the submission of clinical and safety documentation if proof is provided that the combinations are based on classical formulations in officially accepted reference books.

The specific regulation for TCM products in Switzerland takes the specific therapeutic system into consideration, characterized by an individual choice and often an individually adapted medicine for each patient. Even if the authorization criteria and the regulatory process are very simplified, a clearly defined safety level is required and the regulation enables Swissmedic to have an overview of TCM products marketed in Switzerland. Consequently market surveillance is possible and if deemed necessary, products with quality or safety defects can be recalled from the market. In addition a standardized Patient Information leaflet defined by the Agency informs patients about the nature and known risks of TCM products.
Dr. Karoline Mathys, Head Sector Market Surveillance
Swissmedic, Swiss Agency for Therapeutic Products

**Swiss TCM Market**

**Medical treatment**
- at least 30 hospitals with specialized TCM units
- ca. 700 medical doctors with a specialization in TCM (ca. 200 use herbs)
- ca. 20 TCM therapists (acupuncturists, herbalists, masseurs, etc., ca. 400 use herbs)

**Wholesale**
- 4 major importers and wholesalers of TCM drugs and TCM medicinal products

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**Swiss Federal Act on Therapeutic products of 1st January 2002**

- Art. 6 TPA: All ready to use medicinal products may only be placed on the market if authorized by Swissmedic (few exceptions, e.g. formulae magistrales)
- Art. 15 TPA: Transitional regulation for products already on the Swiss market without authorization before 2002 based on previous legislation
- Products can remain on the market if authorization request is submitted by end 2002 till decision is taken
- 5000 requests submitted by December 2002

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**Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products (KPAV/OMEdKol of 22 June 2000)**

**Development of the specific regulation for Asian (TCM) products by an expert group incl. external experts:**
- the Swiss therapists organisation (SBO-TCM)
- The Swiss TCM industry
- Medical doctors trained in TCM
- GMP experience in China, Taiwan

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**Analysis of the situation (1)**

- Swiss marketing authorisation holder typically imports and distributes products, which are collected and processed by a foreign manufacturer
- Swiss wholesalers import large numbers of different TCM-products (single drug products, complex mixtures)
- TCM-products are highly complex mixtures of natural origin which might impair traceability back to the source
- The foreign manufacturer is often located in a country not covered by an MRA or FICOS (e.g. China, Taiwan, India)
Analysis of the situation (2)

Three product „categories“
1) simple drug products (e.g. granules, powders)
2) classical combinations – description in standard books (granules, powders, glycerin, …)
3) fixed combinations – indication labeled, promoted separately

1) and 3) without specific indications labeled are used by TCM therapists and medical doctors trained in TCM
3) Promotion for „public use“ by non specialists

Analysis of the situation (3)

1+2) long traditional use products (decades in China)
    – basic safety information available
    – prescription, use by trained persons
    – regular authorization requirements difficult applicable
    (new „both sides“)
    – simplified authorization procedure

3) Branded products with indication labeled for „public use“ by persons without TCM knowledge
    – authorization requires documentation on safety, quality and efficacy
    – no special regulation procedure

Ordinance on complementary and herbal medicinal products (KPAV/ CAMédocophy of 22nd June 2006)

➤ Marketing authorization for well-established or traditional used products with indication
➤ Simplified marketing authorization for traditional use without indication
➤ Notification procedure for traditional use without indication and compliance with the List T&C

Simplified marketing authorization for traditional use products without indication

Art. 26 CAMédocophy / no documentation on clinical trials required:
➤ Products only provided on prescription or recommendation of qualified doctors or therapists
➤ Substances are contained in Chinese medicine for several decades
➤ Substances are monographed in official pharmacopoeias or in recognized reference texts
➤ Sufficient scientific literature available in an official language of Switzerland or in English to guarantee the appropriateness and safety by specialists qualified in Chinese medicine
➤ the medicinal products are placed on the market only under their technical name – conditions specified by Swissmedic
➤ Quality documentation available
➤ Fixed combinations according to formulas in approved bibliographic literature and used as medicines in modern countries for ≥ 15 years

Notification procedure for TCM products without indication

➤ Premises for notification (Art. 27): In addition to Art26 CAMédocophy:
    ➤ Only active compounds which comply to the Swissmedic List for Traditional Asian Substances (TAS)
    ➤ Herbal or herbal origin
    ➤ Substance monographed in Ph. Eur., Ph. Hebr. or PPRC
    ➤ Approved bibliographic data available on safety and traditional use
    ➤ No indication on product
    ➤ Only oral or external use
    ➤ Specifically trained physicians or therapists responsible for prescription or recommendation of therapeutic use (not individual dose)
    ➤ Recorded use of multiple decades for simples
    ➤ Fixed combinations according to formulas in approved bibliographic literature are used as medicines in western countries for ≥ 15 years
    ➤ Quality documentation must be submitted on demand of Swissmedic

Information of patients

➤ Labeling requirements defined informing about the nature of the product, composition…
➤ Standard Patient Information leaflet (PIL) required informing user about the nature of the product, precautions, restrictions…
➤ PIL already used by some companies even if authorization is still ongoing (information about responsible company but without authorization number)
Legal framework of Traditional Chinese Medicine in Europe; Regulation in Switzerland

All information available (German, French, partly English)

- www.swissmedic.ch > product group: „complementary and herbal medicine“ > Rechtstatte, Verordnungen, Anleitungen (de) or lois legisfls, ordonnances (fr)
- www.swissmedic.ch > home > contact
- karoline.mathys@swissmedic.ch

Simplified regulation for TCM products
Swiss Experience until 2010 (1)

- no applications yet finished as quality documentations submitted not sufficient – return to companies
- GRP inspection audits of manufacturers pending or ongoing
- marketing authorisation holder is liable for the quality and must prove towards Swissmedic that the quality is assured

But
- better awareness of quality requirements by companies importing and distributing TCM products in Switzerland

Simplified regulation for TCM products
Swiss Experience until 2010 (2)

- Swissmedic has a list of all TCM Products legally on the Swiss market incl. composition
- In case of safety signals the recall of products on the Swiss market is possible (e.g. pyrrolizidine alkaloids containing products, Asarinum containing products)
- Standardized patient information is already used by some companies
- better information of patients
2.2 Legal perspectives

Mr Markus AMBROSIUS
Lawyer, Germany

Legal Framework of the TCM in Europe

Legal Perspectives

Outline
A. Regulatory Status and Legal Framework
B. Requirements for practicing TCM
C. Perspectives for regulating TCM

Regulatory Status of TCD
- Traditional Chinese drugs (TCD) are an important part of TCM
- TCM as a medicinal concept that is not limited to TCD
- Regulatory focus is on TCD

Traditional Chinese Drugs
- Herbal origin
- Animal origin
- Mineral origin
- Most are of herbal origin

Current Regulatory System - an Option?
- EU system focuses on standardized medicinal products
- Traditional Chinese preparations often contain several herbal substances (individual preparations)

Concept of Traditional-use Registration
- A long tradition of medicinal use (at least 15 years in EU) is the surrogate for clinical data
- Experience in third countries cannot automatically replace traditional use in Europe
TCD as medicinal products
- TCD as herbal medicinal products
- TCD as food supplements, "herbs", non-pharmaceuticals
- Non-licensed use
- Therapists instead of medical doctors

Options of TCD today
- Formula magistralis
- Formula officinalis
- Named patient use

Requirements for Practising TCM
- Harmonised qualification standards for regulated professions
- Regulated education and training
- Specific requirements for TCM do not exist

Knowledge on TCM/TCD in Europe
- Extent of use in Europe
- Why TCM?
- What about traditional medicines from other parts of the world?

Addressees of Regulatory Activities
→ Pharmacists
→ Prescribers
→ Patients

Development of monographs that cover herbal substances used in TCD
- Ensure that these monographs are used by pharmacists
- Network that focuses on the quality and safety of TCD
- Implementation of an information policy regarding quality and safety of TCD
Thank you very much for your attention!
Session theme: Practice of TCM in Europe
Session Chair:

Dr Christian KALCHER
Vice-Chair of the Committee of Experts CD-P-PH/PC, Federal Ministry of Health, Austria

Speakers:

Dr Yan MA
Medical University Vienna, Austria

Mr Albert L. De VOS
European Traditional Chinese Medicine Association (ETCMA)
3.1 Official training courses for professionals practicing Traditional Chinese Medicine (TCM)

Dr Yan MA
Medical University Vienna, Austria

Traditional Chinese Medicine (TCM) is one of the oldest forms of medicine in the world. There has been a growing interest in TCM among consumers and also among the scientific research community and institutions. TCM has been especially focused on basic and clinical research of cancer and cardiovascular diseases; safety and quality control issues and chemical and pharmacological research of ginseng and so on. The increasing utilization of TCM contrasted with a lack of training and education at medical schools and medical universities. Therefore, TCM training and education programs at public universities are being built up gradually in the last ten years in the United States, in Canada, in Australia and also in many European countries.

In the last ten years TCM has made a great effort of modernization and integration with Western Medicine in Italy. The Italian people appreciate the benefits of TCM but its diffusion in the Western countries still meets some difficulties: Insufficient knowledge by the public of the resources and the effectiveness of TCM and its branches; distrust of the TCM products; scarce information is given to the medical environment; preparation and updating of TCM practitioners is often insufficient; scarce circulation of the scientific information often published only in Chinese and insufficient integration between TCM and Western Medicine [1]. To obviate these problems, the Italy China Foundation has signed a Convention with Centro Studi So Wen, active in Italy since 1974 in the field of TCM medical training and education, through six centers displaced in Italy with more than 400 physicians presently being trained in TCM including acupuncture and Chinese herbal medicine and over 2500 medical alumni. The university course “Traditional Chinese herbal Medicine” in collaboration with the University of Pharmacy of Florence was the first European course addressed to pharmacy experts in the specific field. Study trips to China at the Henan TCM University were organized by the Italian Society of TCM. Since November 2007 a program of e–learning accredited for Medical Continuing Education is activated for: updating Italian acupuncturists; basic and advanced training for physicians in acupuncture and Chinese herbal medicine; basic training for chemists in Chinese herbal medicine; information for Italian physicians about the indications of acupuncture and Chinese herbal medicine.

The complementary and alternative medicine (CAM) therapies in Germany were introduced to the Charité University Medical School in the Berlin reform curriculum in 2005 [2]. The CAM seminars provide basic knowledge about naturopathy, homeopathy and TCM, plus their utilization, empirical research, and underlying philosophies. Experiential and dialogical didactic techniques are employed. Students evaluated the seminars using the “Heidelberg Inventory for Educational Evaluation” program and demonstrated that the high support for university CAM education reflects the students’ desire for more knowledge.

Middlesex University is one of the oldest pioneers and education providers for TCM in the UK and in Europe. Its four years full-time Bachelor program is the first course of its kind in the world outside China [3]. Since its establishment in 1996, the course has been running successfully for more than ten years with students from many countries. Middlesex is unique in its approach to teaching TCM. The two main components, acupuncture and Chinese herbal medicine, are taught as an integrated whole rather than as two separate courses. This follows the traditional pattern of teaching in China, thereby retaining its authentic form. The lecturers, both at Middlesex University and its clinic where the student practice, are specialists in their fields, many of whom have taught and practiced in the best universities and hospitals in China. The students learn the Mandarin language in
the course which not only gives them a grasp of Chinese and an understanding of traditional medicine concept; it also comes in useful when students visit China for work experience or for their Master studies.

In Austria there are some different forms of training and education offered by private organizations and universities since several years. Recently a Curriculum of TCM education for Austrian doctors was developed at the Medical University of Vienna. This program is designed to meet or surpass the highest available standards required for professional licensing in Austria and also in Europe. The TCM course will be offered as a postgraduate program with a degree of “Master of TCM Science”. The duration of the TCM training will be 2.5 years with 660 academic hours and include 90 ECTS (European Credit Transfer System) points. TCM course at the Medical University of Vienna is a joint education program supported by the Austrian Federal Ministry of Health and the Chinese Ministry of Health and will be joined by Austrian TCM institutions and Chinese medical institutions. TCM experts from Austria, China, UK and other European countries will join the teaching program, which has been evaluated in China as well as in Austria by Chinese professors of the China Academy of TCM and Beijing University of Chinese Medicine and TCM experts in Austria. We consider that this model of training and education can be usefully adopted and further developed in Europe in order to contribute to the diffusion of TCM in the West.

Putting together we can conclude that the TCM training and education programs in Europe are multitudinous in different forms in different countries. The regular teaching courses have been established at different levels, which lead to professional qualifications of Certificate and Diploma. With an ever-increasing number of people integrating TCM into their health care regiment, there has never been a more exciting time to consider a career in TCM. However, the highest standards of training and education are essential for successful and rewarding practice. The training and education of TCM at the university will have an increasingly important role in promoting the use and scientific evaluation of acupuncture and Chinese herbal medicine for the public benefit. TCM training and education programs may not be the same as in China, but they should be joined training and education program supported by Chinese TCM universities and European medical universities. The regulatory and educational framework of TCM should be established in Europe for promoting the official training and practice of professionals. The development of knowledge, understanding and skills and conducting research on evidence-based practice should bring TCM into cornerstone for developing future medicine (West meets East) in Europe and in the world.

References:


Official training courses for professionals practicing Traditional Chinese Medicine (TCM)

Yan Ma
Vienna General Hospital
Medical University of Vienna

Development of TCM Education in the World

TCM training and education programs at public universities are being built up gradually in the last ten years in Japan, in Korea, in the United States, in Canada, in Australia.

Also in many European countries, such as in Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Ireland, the Netherlands, Sweden, Switzerland, the UK and Austria.

Development of TCM Education in Europe

The university course "Traditional Chinese herbal Medicine" at the University of Pharmacy of Florence was the first European course addressed to pharmacy experts in the specific field of TCM.

The complementary and alternative medicine (CAM) therapies in Germany were introduced to the Charité University Medical School in Berlin by the reform curriculum in 2005.
Proceedings of Traditional Chinese Medicine (TCM) Expert Workshop, 28 October, Strasbourg

Dr. Yan MA
Official training courses for professionals practicing Traditional Chinese Medicine (TCM)

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**Development of TCM Education in Europe**

- Middlesex University is one of the oldest education providers for TCM in the UK and in Europe. Its four years full-time Bachelor program is the first course of its kind in the world outside China.

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**Development of TCM Education in Europe**

- Middlesex University is one of the oldest education providers for TCM in the UK and in Europe. Its four years full-time Bachelor program is the first course of its kind in the world outside China.
- Recently a Curriculum for the post-graduate university course of TCM at the Medical University of Vienna (MUV) has been developed. This program is designed to meet or surpass the highest available standards required for professional practicing TCM in Austria and also in Europe.

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**Development of TCM Education in Austria**

- TCM is getting more popular in Austria.

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**Development of TCM Education in Austria**

- TCM is getting more popular in Austria.
- 30% of patients have used some kind of complementary and alternative medicine (CAM) treatment including TCM and 80% of patients are interested in utilization of complementary medicine treatment.

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**Development of TCM Education in Austria**

- TCM is getting more popular in Austria.
- 30% of patients have used some kind of complementary and alternative medicine (CAM) treatment including TCM and 80% of patients are interested in utilization of complementary medicine treatment.
- A post-graduate university course of Traditional Chinese Medicine (TCM) will be started soon at the Medical University of Vienna.

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**Does the Medical University of Vienna have the capability for TCM training and education?**

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Proceedings of Traditional Chinese Medicine (TCM) Expert Workshop, 28 October, Strasbourg

Dr Yan MA
Official training courses for professionals practicing Traditional Chinese Medicine (TCM)

History
The Medical Faculty of the University of Vienna was chartered in 1365
The old Vienna General Hospital was founded in 1784 and established as the leading hospital in Europe

Medical University of Vienna - Today
Status
- employees (incl. teaching, admin., clerical, technician): 5,000
- full time academic staff: 2,500

Medical University of Vienna - Today
Medical Education at the MUV
Degree programs:
- MD program: 660 (740) students/year
- Dentistry D program: 80 students/year
- Medical Informatics: MA program, since 2006
- MD/PhD (English language program)

Medical University of Vienna - Today
Post-graduate Education at the MUV
- Clinical Research (MD)
- Gender Medicine (MD)
- Public Health (MPH)
- Toxicology (MD)
- Interdisciplinary Pain Management (MS)
- Medical Hypnosis
- Dental Hygiene
- Periodontology (MD)
- Management in Nursing and Care
- Pedagogical Training in Nursing and Care
- Oral Implantology (MD)
- Prosthetics (MD)
- Medical Physics (MD)
- Health Care Management (MBA)
- TCM (MS)

University Course of TCM at the MUV
Post-graduate University Course of TCM is being prepared since 2004 at the MUV
- Structured intra- and extramural continuing medical education & training program
- Degree program (MS)
- National and international teaching staff

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61
University Course of TCM at the MUV

Foundations and Practice of Traditional Chinese Medicine

- Duration: 2.5 years
- 90 ECTS (European Credit Transfer System), 45
  Semester hours/660 Academic hours
- Qualification requirements for admission: graduated
  study of human medicine; dentistry; veterinary medicine;
  pharmacy and other disciplines (if relevant work
  experience in the field of TCM is demonstrated).

Dr. Yan MA
Official training courses for professionals practicing Traditional Chinese Medicine (TCM)

University Course of TCM at the MUV

Curriculum for the University Course of TCM

- Based on the Curricula of
  - The Capital Medical University of Beijing
  - Beijing University of Chinese Medicine
  - Shanghai University of Traditional Chinese Medicine
  - Nantong University of Traditional Chinese Medicine
  - Shandong University of Traditional Chinese Medicine

University Course of TCM at the MUV

Experts evaluation meetings for the Curriculum of TCM

- Austrian Federal Ministry of Health and Chinese Ministry of
  Health organized the evaluation meetings in China and in Austria
- First evaluation meeting was held on September 10th to 18th 2007
  in Beijing
- Second evaluation meeting was held on May 28th to 30th 2008 in
  Beijing
- Third evaluation meeting was held on June 5th to 6th 2008 in
  Beijing.

University Course of TCM at the MUV

- Experts meeting was held on May 11th to 12th 2010 in Beijing.

University Course of TCM at the MUV

Evaluation of the TCM lectures at the MUV by Students

- 2006, 2009 and 2010
  Introduction of TCM - Theory, Diagnosis, Therapy and
  Research
- More than 300 students and medical doctors from MUV,
  VW, Vienna University of Technology, University of Natural
  Resources and Applied Life Sciences and the hospitals.
- Evaluations of the lecture by students and doctors (100 %)
  were very well.
Does the Vienna General Hospital have the capacity for practicing TCM?

TCM Practice at the Vienna General Hospital

- A teaching hospital of the MUV
- Many Departments are applying some kind of TCM treatments.
- Department of Physical Medicine and Rehabilitation
- Department of Cardiology and Gynecology
- Division of Cardiology
- Division of Rheumatology
- Department of Dermatology
- Department of Psychiatry and Psychotherapy
- Department of Physiotherapy and Occupational Therapy
- Department of Ophthalmology and Optometry

All departments agree to support the training program of the University Course of TCM.

TCM Practice at the Vienna General Hospital

Sino-Austrian Diagnosis, Treatment and Research Center of Cardiovascular Diseases

Head of the Sino-Austrian Center:
Prof. Dr. Gerdt Maier, head of the Division of Cardiology at the Vienna General Hospital.

Both sides agree to support the training program of the University Course of TCM - Clinical Observation and Clinical Internship.

TCM Practice at the Vienna General Hospital

Molecular and Clinical Research in Traditional Chinese Medicine

- Effects of traditional Chinese herbal medicine on myocardial infarction in a rat model.
- Comparison of traditional Chinese medicine and Western medicine in the treatment of metabolic syndrome and diabetes.
- Quality control of Chinese medical herbs for prevention and therapy of age-related diseases.
- Effects of acupuncture on chronic non-specific back pain.

University Course of TCM at the MUV

Conclusions

- Education of TCM at the MUV is very welcome by students and medical doctors. MUV and VGH have capability and capacity for TCM training, education and practicing.

University Course of TCM at the MUV

Conclusions

- Education of TCM at the MUV is very welcome by students and medical doctors. MUV and VGH have capability and capacity for TCM training, education and practicing.
- TCM education at the University level should be a joint education program supported by Chinese TCM universities and European medical universities.
Conclusions

- Education of TCM at the MUV is very well received by students and medical doctors. MUV and VGH have capability and capacity for TCM training, education and practicing.
- TCM education at the University level should be a joint education program supported by Chinese TCM universities and European medical universities.
- The regulatory and educational framework of TCM should be established in Europe for promoting the official training and practice of professionals. The development of knowledge, understanding and skills and conducting research on evidence-based practice should bring TCM into common use for developing future medicine (West meets East) in Europe and in the world.

List of Co-operations

- China Academy of TCM
- Capital Medical University of Beijing, China
- Peking University of Traditional Chinese Medicine, Beijing, China
- Nanjing University of Traditional Chinese Medicine, Nanjing, China
- Shanghai University of Traditional Chinese Medicine, Shanghai, China
- Midwessex University, London, UK
- University of Vienna, Austria
- Medical University of Graz, Austria
- University of Graz, Austria

Acknowledgments

Medical University of Vienna
University of Vienna, Austria
Medical University of Graz, Austria
University of Graz, Austria
China Academy of Chinese Medical Sciences
Capital Medical University of Beijing, China
Shanghai University of Traditional Chinese Medicine, Shanghai, China
Peking University, China
Nanjing University of Traditional Chinese Medicine, Nanjing, China
Midwessex University, London, UK
Austrian Federal Ministry of Health
Chinese Ministry of Health
Europe-Pacific Union, Austria
3.2 Perspectives on professional standards

Practice of TCM in Europe

Mr Albert L. De VOS
European Traditional Chinese Medicine Association (ETCMA)

The European TCM Association is unique. It represents approximately 9000 practitioners in 14 Associations spread over 12 European countries. One of the aims is to establish standards in education of TCM practitioners and to optimize cooperation between the countries/associations. One of the issues is who is capable of training the students; Colleges or Universities? Another unresolved question is that of the level of training required (BA/MA?).

In Norway, The Netherlands and the UK, initiatives are already underway in this field.

We will also discuss the question of who may prescribe Chinese Herbs and who will be responsible for ensuring quality.

My pragmatic opinion is that depending on producers outside the EU to ensure the safety of Herbs is not a solution.

For the health of consumers/patients it is vitally important that the European associations cooperate and not be divided by diversity in national laws or other sentiments. Patients now cross borders for a wide variety of treatments. They should be protected against malpractice or badly schooled practitioners.
Mr Albert L. de Vos

Perspectives on professional standards Practice of TCM in Europe

Mission Statement ETCMA

- ETCMA is a forum for exchanging information and promoting cooperation between its members in order to establish TCM as a distinct medical modality based on high educational standards.
- By creating comparable accreditation systems in each member country we aim to create freedom of movement for practitioners across Europe.
- Access to information and political lobbying will be based on trust and open debate.

Standards

- Training professionals
- Training and competencies

Europe

- Level of training
- Differences
- Goals
BREAK-OUT SESSIONS
BREAK OUT SESSION 1

A legal framework in Europe taking account of the specific approaches used in TCM

Moderator:

Dr Katrin JAHN, Swissmedic
Swiss Agency for Therapeutic Products, Switzerland

Rapporteur:

Mr Markus AMBROSIUS
Lawyer, Germany
Breakout session (BS 1)

A legal framework in Europe taking account of the specific approaches used in TCM

Dr. Ralph John, Swiss Agency for Therapeutic Products
Dr. Marku Ambrosse, Austrian Agency for Medicines

1. Possible options for norms

Suggesting comparable qualification 'training' education for practitioners in Europe

Basic requirement for qualification, education, continuous training should be made mandatory

Contents to be elaborated in consultation with professional associations/bodies/overseeing authorities

2. Possible options for norms

Supporting comparable vigilance systems in Europe

Reporting should be mandatory, authorities to be informed,

- TCM product
- Prerequisite homoeopathic definition

3. Possible options for norms

Supporting comparable model/matched information systems in Europe

For patients/consumer

Feed back to safety authorities recommended

4. TCM Products

a. Basic requirements for marketing authorisation

Controversial discussion: current MA system should be applied, some of the problems with TCM were dealt some decades ago with conventional medicines

Some experts supported Swiss approach quality & GMP: EU accepted by some experts

Issue raised: same preparation as in original TCM "proof of tradition"

b. Market analysis / Quality of the products

Recommended to have more data - inventory desirable, also with regards to vigilance

4. TCM Products
BREAK OUT SESSION 2:

TCM: Professional standards, practice and training courses

Moderator:
Professor Dr Gertrude KUBIENA
Advisory Board TCM of the Federal Ministry of Health, Austria

Rapporteur:
Dr Reinhard LÄNGER
AGES PharmMed, Austria

Break-out session conclusions BS 2

### Questions

- How can the knowledge be maintained or increased at universities or should it be transferred to other institutions?
- What are the basic needs for pharmacists dealing with herbal substances of the TCM?

### Questions

- Where is the best environment for such training courses? Universities, postgraduate training institutions, EDQM, lobby of pharmacists?
- Who takes responsibility for the training of pharmacists?

### Questions

- How can these skills be trained? Theory, practical courses, duration, equipment, trainers?
- Development of a European standard for quality control of TCM herbs and products?

### Questions

- Quality control of medicinal products, patients' safety, counterfeit medicines?
- Training other practitioners

### Questions

- Basic curriculum for TCM-Practitioners, including pre-education?
- TCM-Pharmacists
- Other professionals?
Questions

- Qualification of TCM teachers and teaching organizations?
- 5. Transitional regulations for hitherto existing teaching organizations and TCM practitioners
BREAK OUT SESSION 3
Access for patients in Europe to reliable information on TCM

Moderator:
Dr Karen PILKINGTON
University of Westminster, United Kingdom

Rapporteur:
Mr Einar MAGNUSSON
Ministry of Health, Iceland
ACCESS FOR PATIENTS IN EUROPE TO RELIABLE INFORMATION ON TCM

EDOM

STRASBOURG

2010

Dr Karen Pilkington

UNIVERSITY OF WESTMINSTER

BACKGROUND AND AIM

The Committee of Experts on Quality and Safety Standards for Pharmaceutical Practices and Pharmaceutical Care (CD-PHP/CPC) 2006/008/R survey on the status of TCM in Europe:

Public health in Europe will benefit from balanced information for consumers and patients and from surveillance of the safety of TCM practices including the use of TCM products.

Aims

Discussion and outline of:

- Options to inform patients and the general public about the benefits, limitations, and risks of TCM in an appropriate and balanced way and to establish safety surveillance of TCM practices including the use of TCM products

CURRENT INFORMATION PROVIDERS

- TCM practitioners, suppliers, manufacturers
- Professional organisations
- Complementary medicine information services
- Medicines and Healthcare Regulatory Agency (UK)
- National Health Service patient information services (UK)
- Medicines Information Centres (UK)
- Chinese Medicine Advisory Service (UK)

UNIVERSITY OF WESTMINSTER

EXAMPLE OF THE PROCESS OF CARE

BACKGROUND

Information-related considerations: consultation
- TCM practitioners are not centrally regulated and registration is currently voluntary
- TCM syndromes (diagnoses) are based on a different framework from conventional medicine
- Prescribing is individualised
- Potential interactions with concurrent drug therapy may not be addressed

UNIVERSITY OF WESTMINSTER

BACKGROUND

Information-related considerations: prescriptions
- Mixtures of herbs are prescribed or supplied
- These often contain multiple (10-15) different herbs
- Species used may differ
- Herbal may be of plant, animal or mineral origin
- Different forms are used: pills, powders, tinctures or extracts from which a decoction or tea is prepared

UNIVERSITY OF WESTMINSTER
BACKGROUND

Information-related considerations: labelling and leaflets
- Quality and quantity of information provided on labels is variable
- There is variation in the language used (Chinese, English, Latin names)
- Some or all of the ingredients may not be listed
- Inclusion of all relevant information for complex mixtures of herbs will be challenging and may not be feasible in some cases

INFORMATION CURRENTLY PROVIDED
- TCM practitioners, suppliers, manufacturers: information on specific herbs, frequently treated problems
- Professional organisations: general information, lists of registered practitioners
- Medicines and Healthcare Regulatory Agency (in UK): general information on herbs, frequently asked questions, safety bullets
- National Health Service information services (UK): limited information for patients, access to information on evidence, safety bulletins, news items
- Chinese Medicine Advisory Service (UK): answers to specific queries

SPECIALIST SOURCES
- Specialist databases
- Monographs
- Specialist websites e.g. Slone-Kettering
- U.S. cancer-related, evidence-based information about herbs, botanicals, supplements
- Published literature
  - May be in Chinese and requires translation

QUERIES REFERRED TO CHIMAS
- Interactions
- Potential
- Suspected
- Safety
- Adverse reactions
- Identification and translation
- Effectiveness
- Mainly originate from pharmacists and doctors

OVERALL CONSIDERATIONS
- Points in the care process when information is required by or for patients
- Type of information and level of detail that is required
- Responsibility for the provision (and collection) of reliable information
- Presentation and publication of information
- Route to the information for patients
**SPECIFIC QUESTIONS**

When is information on TCM most likely to be required by patients?
- before consulting a TCM practitioner/buying a product
- during the consultation
- after consultation/when collecting prescription
- if the person experiences side effects or an adverse event

**SPECIFIC QUESTIONS**

What reliable information on TCM is needed?
- General information on TCM?
- Terminology?
- What is TCM used for?
- Efficacy and effectiveness?
- Safety?
- What to expect in a consultation?
- Dosages and preparations?
- Regulatory status?
- Availability?
- Costs?
- List of qualified and certified TCM practitioners

**SPECIFIC QUESTIONS**

Who should be responsible for providing reliable information (and collecting safety data) on TCM?
- WHO?
- EUCOM?
- Ministries of Health?
- Medicine Agencies?
- Food authorities?
- The TCM industry?
- TCM professional organisations?
- Safety agencies

**SPECIFIC QUESTIONS**

Where should reliable information on TCM be presented/published?
- In the Chinese Pharmacopoeia?
- In the European Pharmacopoeia?
- On a dedicated website?
- Integrated into existing national or international health information websites?
- On websites of MHLW/Medicine Agencies?
- TCM – Literature
- Bulletins and newsletters
- Labels and leaflets?
- Via specialist advisory service

**SPECIFIC QUESTIONS**

How should reliable information on TCM be provided?
- Direct to the general public?
- Direct to patients?
- Via TCM practitioners?
- Via medical doctors?
- Via nurses?
- Via pharmacists?

**ACKNOWLEDGEMENTS**

I would like to thank the following organisations for discussions that were invaluable in informing this presentation:
- Asian and South East Regional Medicines Information Centre
- National CAM information centres in Denmark, Norway, and the USA
- National Institute for Health Research and the USA
- MHLW/Medicine Information Centre
- UK Traditional Medicine Advisory Service

And the first author for his input into this session for valuable input in developing the specific questions.
Break out Session Conclusions and Panel discussion:

Approaches to provisions for practices in TCM and practical assistance for implementation

Moderator:
Dr Friederike ZECHMEISTER-MACHHART
Federal Ministry of Health, Austria
Breakout session 1:
A legal framework in Europe taking account of the specific approaches used in TCM

Moderator: Dr Katrin JAHN; Rapporteur: Mr Markus AMBROSIUS

- Can comparable qualification/training/ (continuous) education in Europe be supported by legal provisions?

The qualification of practitioners, basic elements of training should be comparable in Europe. A legal basis is desirable.

Standardised training depends on the target, the involvement of relevant associations in the establishment of training contents is desirable.

Question: how to ensure that ‘body of evidence’, core principles of TCM are in line with the training concepts?

Comment: Hungary has a comprehensive regulation of CMA (Complementary and alternative medicine) which may be used as inspiration.

- Can vigilance systems that are comparable within Europe be supported by legal provisions?

Serious adverse events should be reported to authorities. Authorities’ feedback and follow-up should be given.

Comment: the participants from the associations reported that adverse drug reactions (ADR) were rare in general, although underreporting was possible, and that TCM was safe in general if carried out by practitioners. Self-medication by patients and purchases by internet was considered dangerous. Currently reporting was not mandatory or harmonised. Reference was made by the participants to the Swiss TCM vigilance system.

Question: how to deal with reporting of ADR through TCM products which are food supplements? Reporting may require definitions, the availability of lists of products and substances used.

What about adverse reactions to TCM as therapeutic medical system?

Comment: pharmacists can prepare magistral preparations of TCM products. There is missing information about genotoxicity and mutagenicity of certain ingredients used in TCM.

- Marketing authorisation procedures – are EU requirements for traditional medicines and well-established use medicines applicable?

Controversial discussion

(Medicinal) product approach vs. comprehensive therapeutical systems approach (in order to evaluate a comprehensive medical system – system biology approaches required – costly/time-resources consuming). The participants considered the Swiss approach towards marketing authorisations of TCM products very interesting.

Question: can the experiences be transferred to other countries in Europe?
As long as products used in TCM can be classified as food supplements, manufacturers/distributors will not be encouraged to apply for marketing authorisation.

Well-established use: question how to judge “long experiences with TCM” in the region of origin: different lifestyles and use in western countries, different approaches to the understanding of vigilance.

“Modernisation” of TCM in region of origin: what should be understood by this – different galenical formulation-dosage forms – impact?

**Breakout session 2:**

**Professional standards, practice and training courses**

Moderator: Professor Gertrude KUBIENA; Rapporteur: Professor Reinhard LÄNGER

It is recommended to

- carry out a complete survey on current training courses in countries in Europe, comparison of curricula taking into account the relevant survey of WHO,
- establish guidelines for qualification/certification of practitioners/pharmacists and guidelines for qualification/certification of trainers,
- include experienced practitioners/pharmacists in training courses,
- teach skills not knowledge,
- develop certificates for practitioners/pharmacists that are accepted all over Europe,
- establish a (training) advisory group (“Training Committee” of senior experts in TCM, supervision & evaluation of the training course and curricula),
- allocate more resources to universities/academic institutions for research in TCM,
- promote cooperation between universities/academic institutions and training courses-develop basic induction modules for TCM in regular university curricula for pharmacists.

**Breakout session 3:**

**Access for patients in Europe to reliable information on TCM**

Moderator: Dr Karen PILKINGTON; Rapporteur: Mr Einar MAGNUSSON

*This is covered by the next conclusion.*

When do patients need information?

- Patients need information at each stage of the (TCM) process.
- The information required may be different at each stage.
- It may be provided by different means and different people.
- There should be some consistency in the approach.

**What information is needed?**

Information is required on various different aspects e.g.

Before taking the decision to use TCM – general information, regulation and lists of practitioners, common uses;

When collecting prescriptions or buying a TCM product – administration, safe use including possible adverse effects related to specific herbs;

**How to deal with internet information?**

General guidance on how to evaluate or select websites

Accreditation or quality standards for websites

Provide (e.g. by EDQM coordinated expert committees?) model information website for countries to implement

A central website with generic information and links to each country

**Who should be responsible for providing information for a model website?**

Some of the information required is already available from reputable organisation and needs to be collated and assessed.

The creation of a model by EDQM coordinated expert committees?

Involvement of professional organizations and other stakeholders for the definition of the model

Cooperation with WHO

**How should information be presented?**

Some consistency in approach is needed

Standard information could be made available on a central website (EDQM?) with links to further (official) information specific to each country

Standardisation of labeling would ensure that basic information is included
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APPENDIX 2: SPEAKERS’ CURRICULA VITAE

Mr Markus Ambrosius
Markus Ambrosius is member of and lecturer for DGRA (Deutsche Gesellschaft für regulatorische Angelegenheiten) since 1999. He is partner of Kanzlei Sträter, a law firm located in Bonn that is specialised in the life science sector for more than twenty years.

His practice covers pharmaceuticals, biotechnology and medicinal devices. He provides advice across the full range of regulatory matters. He also speaks and writes regularly on life science issues

Professor Dr Rudolf Bauer, Ph.D.
Dr Rudolf Bauer studied pharmacy at the University of Munich from 1976-1980; 1984 graduation as Ph.D. at the Institute of Pharmaceutical Biology, University of Munich, under the supervision of Professor Dr. H. Wagner; 1993 – 2002 Associate Professor at the Institute of Pharmaceutical Biology, University of Düsseldorf; since 2002 he is full professor of pharmacognosy at University of Graz, Austria, and since 2004 Head of the Institute of Pharmaceutical Sciences at University of Graz. He has long experience in natural product chemistry, analysis and the bioassay-guided isolation of constituents from medicinal plants. He has published more than 260 research papers. He is past president of the Society for Medicinal Plant and Natural Product Research (GA) and Editor of Planta Medica. Professor Bauer has been active in the development methods for quality control of Chinese herbs for 19 years. He is member of the expert group 13A and of the working group on TCM of the European Pharmacopoeia Commission and is actively involved in the development of monographs of Chinese herbs for the European Pharmacopoeia. He is also member of the TAM Advisory Board of the Austrian Ministry of Health. Together with Professor Litscher (Medical University of Graz) he is heading the TCM Research Center in Graz.

Mr Albert L. de Vos, BHSc, LAc.
Albert de Vos is Chief Executive Officer of the European TCM Association and Vice President of the Dutch Association of Acupuncture. He has been working as a physiotherapist and acupuncturist for more than 30 years. Over time his goal emerged to organise the acupuncture/TCM field in a professional way, both in The Netherlands and in Europe. ETCMA is the only European association existing in the field.

At this moment much is carried out by “well meaning” professionals. However, quality management is needed in order for the field to mature. It is also in order to provide standards for schooling and to create a solid structure for research.

Dr Katrin Jahn, Dr. rer. nat.
Dr Katrin Jahn studied Pharmacy at the University of Hamburg and received her pharmaceutical license in 1986. In 1998 she was awarded a doctorate of science also from the University of Hamburg. She completed two postgraduate courses of studies in Toxicology at the University of Leipzig (2002, “Fachpharmazeutin für Toxikologie”) and in Drug Regulatory Affairs at the Rhenish Friedrich Wilhelm University in Bonn (2006, “Master of Drug Regulatory Affairs”). In her master thesis she compared the legal framework of Switzerland and the Community for marketing authorisation of products used in traditional Chinese medicine. Since 2004 she has been working in Switzerland, first as the Responsible Person (equivalent to “qualified person”) at a company manufacturing and distributing traditional Chinese medicines and then from 2007 as a Quality Reviewer at Swissmedic, Swiss Agency for Therapeutic Products.
**Dr Christian Kalcher, Ph.D.**

Dr Christian Kalcher is a civil servant in the Federal Ministry of Health in Austria. He holds a Ph.D. (1976) in pharmaceutical chemistry from the University of Vienna. From 1977 to 1991 he was assessor in the former Federal Institute for pharmaceutical assessment of drugs. He was extensively involved in the assessment of the pharmaceutical-chemical part of the dossier in the marketing authorisation procedure of medicines. Since 1991 he is serving in the Austrian Federal Ministry of Health in the unit dealing with international pharmaceutical affairs. He participated in the EU Council Working Party on medicinal products; he was Member of the EMEA-Management Board (2002-2005). At present he is an alternate Member of the EMA-Management Board. From 1993-2007 he represented Austria in the former Committee of Experts on Pharmaceutical Questions of the Council of Europe (Partial Agreement).

**Dr Susanne Keitel**

Dr Susanne Keitel is a licensed pharmacist with a Ph.D. in pharmaceutical technology. Her work experience includes 10 years in pharmaceutical development in industry, with five years as Department Head of “Pharmaceutical Development/Oral Dosage Forms” at the former Schering AG, Berlin. From 1997 to 2005, she held the position of Division Head Pharmaceutical Quality at the Federal Institute for Drugs and Medical Devices (BfArM), Germany. She additionally served as Acting Head of the Division European Procedures from November 2003.

From July 2005 to October 2007, Susanne Keitel was Head of EU, International Affairs at BfArM. During her time with BfArM, she represented the agency in a number of EU committees, including the Joint CHMP/CVMP Quality Working Party (QWP), the EMEA Paediatric Working Party and the European Commission’s Notice to Applicants Group. She was actively involved in the International Conference on Harmonization (ICH), where she acted as the EU topic leader and rapporteur for the ICH guidelines on stability testing and pharmaceutical development. On a national level, she was, from 2001 to 2007, Chair of the German Pharmacopoeia and the German Homeopathic Pharmacopoeia. Since October 2007, Susanne Keitel is Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe in Strasbourg.

She also lectures in the postgraduate course “Master of Drug Regulatory Affairs” at Bonn University, where she is responsible for the module on the quality dossier. In 2009, Dr. Keitel was elected as corresponding Foreign Member at the French Académie Nationale de Pharmacie.

**Professor Dr med. Mag. phil. Gertrude Kubiena**

Dr Gertrude Kubiena obtained his graduations in Medicine (MD) 1963, Master of Philosophy (Sinology) 1997, University of Vienna. He is a General Practitioner and Ear, Nose Throat specialist.

Since 1972 acupuncture, since 1995 Chinese Herbal Therapy. Since 1999 organisation of and lecturing for the 2,5 years lasting postgraduate training for physicians (PG TCM), advanced medical students, pharmacists and veterinaries. October 2010 the 6th PG started. Graduated MDs have the possibility to achieve the diploma “Chinese Diagnostics and Herbal Therapy” of the Austrian Board of MDs. This diploma was established in 2004 in collaboration with the established Austrian TCM-training associations.

President of MedChin (a non-profit organization for education in Chinese Healthcare). Author/co-author of about 30 books, 190 papers about TCM; ~30 visits to China, mostly for TCM-training.

Actual target: Establishment of EU terms of reference for TCM practitioners, emphasising on the required education, unified lines for TCM-curricula.
**Associate Professor Dr Reinhard Länger, PhD**

Dr Reinhard Länger is Deputy Head of the Department for herbal medicinal products and homoeopathics at the Austrian Medicines & Medical Devices Agency (AGES PharmMed). He studied Pharmacy at the University of Vienna. After the PhD (1986) and habilitation in pharmacognosy he became Associated Professor at the University of Vienna (1997). Primary research topics were pharmaco-botany and quality assurance of herbal drugs. He was lecturer for students of pharmacy and responsible for practical courses in botany and pharmacognosy. In 2006 he changed to the Austrian Medicines Agency and is now responsible for the quality assessment of herbal medicinal products. He is involved in the classification of borderline products as well as in general regulatory issues of herbal drugs and herbal preparations. He is member of the Monographs and Lists Working Party of the European Medicines Agency (EMA), member of the national expert group for the Austrian pharmacopoeia as well as of the working group on microbiological quality of herbal drugs at the EDQM. He is author of about 80 original research articles and of several scientific and popular scientific books on herbal medicines and medicinal plants. At the EMA he serves as rapporteur for EU community monographs on herbal substances and preparations thereof.

**Associate Professor Dr. Yan Ma, BSc, MSc. Ph.D, chin. M.D.**

Dr Yan Ma is Head of the University Course of Traditional Chinese Medicine (TCM) at the Medical University of Vienna, Head of the research group of Molecular and Clinical Research in Traditional Chinese Medicine and Deputy of the Sino-Austrian Diagnosis, Treatment and Research Center of Cardiovascular Diseases at the Vienna General Hospital. He is an Associate Professor for Pathophysiology and Allergology at the Department of Pathophysiology, Center of Pathophysiology, Infectiology and Immunology, Medical University Vienna. She holds a PhD (1999) and an MSc (1994) in biochemistry from the University of Vienna, a chin. MD (1986) from the Nanjing University of Traditional Chinese Medicine and a BSc (1983) from the University of Nanjing. She was a medical doctor at the Jiangsu Province Hospital and Deputy of the Laboratory Centre of Immunology, Nanjing Cancer Research Center of the Jiangsu Province Hospital in Nanjing, China. She joined EU Research Framework Programs FP5 (Plant food allergies: field to table strategies for reducing their incidence in Europe) and FP6 (The prevalence, cost and basis of food allergies across Europe). She is joining the research program of the Austrian TCM Research Cluster (Age and Related Diseases) supported by the Austrian Federal Ministry of Science and Research and the Austrian Federal Ministry of Health with the topic of “Effects of a traditional Chinese herbal medicine formula on myocardial infarction in a rat model”. She is a Member of the European Academy of Allergy and Clinical Immunology (EAACI); Consortium for Globalization of Chinese Medicine (CGCM) and Herbal Medicinal Products Platform Austria (HMPPA) - TCM Research Cluster Austria.

**Mr Einar Magnusson**

Einar Magnusson is the Head of Pharmaceutical Department at the Ministry of Health in Iceland. He has long time experience of working as a pharmacist in a pharmacy, in production of medicinal products, and as a part time lector at the University of Iceland. He was Pharmaceutical Consultant for WHO Regional Office for Europe in Denmark from 1995 – 1996 and Pharmaceutical Adviser at Ministry of Health in Hanoi Vietnam for the Vietnam-Sweden Health Cooperation from 1999 – 2002. He has also worked as a Short Term International Consultant for WHO and other international organisations in different other countries, like Andorra, Bosnia, Bulgaria, Faroe Islands, Federal Republic of Yugoslavia, Georgia, Malta, Romania, Tanzania, Turkmenistan and Uzbekistan.

**Dr Karoline Mathys Badertscher**

Dr Karoline Mathys is Head of the Sector Market Surveillance and Member of the Management Board of the Swiss Agency for Therapeutic Products, Swissmedic. She holds approbation as a pharmacist (1988) from the University of Bern, Switzerland. From 1989 to 1993 she was Doctorate and Assistant at the Department for Pharmacology and Phytochemistry at the University of Bern. 1993 she joined the Intercantonal Office for the Control of Medicines (predecessor of Swissmedic) as quality reviewer and head laboratory for the control of
Herbal Medicinal Products. From 1995 till June 2007 Dr. Karoline Mathys was responsible for the authorisation and market control of Complementary and Herbal Medicines in Switzerland. She was responsible for the elaboration of the new Ordinance on Complementary and Herbal Medicinal Products, in force since 22nd July 2006. In July 2007 she was promoted Head of the new Sector Market Surveillance including the Divisions Medical Devices, Market Control of Medicinal Products and Safety of Medicines. She is Swiss delegate of the Steering Committee, the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH/EDQM), Member of the Swiss Pharmacopoeia Commission and alternate Member of the Swiss Delegation of the European Pharmacopoeia Commission as well as member of the Permanent Forum on International Pharmaceutical Crime (PFIPC).

**Professor Emilio Minelli**

Emilio Minelli is Vice Director of the WHO Collaborating Centre for Traditional Medicine at State University of Milan. He has a degree (1976) in Medicine and Surgery at State University of Milan. He is Expert Practitioner in Acupuncture, Traditional Phytotherapy and Homeopathy. From 2000 until now he is Professor on contract of Acupuncture at State University of Milan and from 1998 until now he is Didactic Coordinator of three specialising courses in Acupuncture, in Phytotherapy and in Nonconventional Medicine and Complementary Techniques at the same university, where in 2005 he has served on Chinese-Italian Joint Committee for the development of activities related to the International Master of Integration between Traditional Chinese Medicine and Western Medicine. From 2003 until now he is Consultant of the Directorate General of Health of Lombardy Region for drafting and implementing the Memorandum of Understanding between the Regional Government of Lombardy and the World Health Organization for activities relating to complementary medicine. From 2000 until now he is Scientific Consultant for implementing research project in the field of Nonconventional Medicine, Hospital “Sacco” and “Civil Hospital of Lecco”.

From 2004 until now he is a European Expert of European Medicines Agency (EMA) for Traditional European and Chinese Phytotherapy. From 2003 until now he is Member of the Editorial Board of Evidence-based Complementary and Alternative Medicine, Oxford University Press. From 1994 until now he is Founder and member of the S.M.P., Société Méditerranéenne de Participation à l’E.C.P.M. (European Council of Doctors for Plurality in Medicine, Brussels). He is cited in scientific literature and is clinical researcher in acupuncture, traditional phytotherapy and homeopathy. He is member of the WHO Expert Advisory Panel on Traditional Medicine. He is author of more than 90 scientific papers in books, international or national scientific journals and conference proceedings.

**Professor Olavi Pelkonen, M.D., Ph.D.**

Olavi Pelkonen has been Professor (since 1986; emeritus since 01/05/2010) and Head of Department of Pharmacology and Toxicology, University of Oulu, Finland (1986-2010). He holds MD (1973) and PhD degrees (1973) at University of Oulu. He was postdoctoral fellow at National Institutes of Health, Bethesda, Maryland (1976-1977) and thereafter been Associate and Full Professor of Pharmacology in Oulu, Finland. His current interests include the development of in vitro and in silico methods for drug development and chemical risk assessment. He is participating in multi-year Pharma projects, with the support from The Academy of Finland, Finnish Technology Research Centre for Innovation and Drug Industry. In 2008, he started Academy-supported scientific project on diet-drug interactions, which includes also herbal medicinal products. He has participated, also as working group leader, in EU COST Actions (B1 in 1986-1998, B15 in 1998-2004 and B25 “Physiologically based Pharmacokinetic and Pharmacodynamic Modelling” in 2005-2009) and coordinator of FP project EUROCYP “Integration of in vitro approaches to study drug metabolism and drug interaction in drug development in man” (1996-1999). He has currently expert roles at ECVAM and EMA (co-opted member in toxicology in HMPC), and advisory roles in Finnish drug development service SMEs. He has been visiting professors in Spain, United Kingdom and Australia. He is author in >300 original and review articles in
international scientific journals and books, mainly on various aspects of drug and carcinogen metabolism and its regulation by genetic, environmental and host factors and he is a 'Highly Cited Researcher in pharmacology and toxicology' (ISI-Thomson). In 2007, he was awarded The Bo Holmstedt Memorial Lecture Award by EUROTOX and in 2010 he gave plenary lecture at WorldPharma2010 in Copenhagen.

Dr Karen Pilkington, B Pharm, MSc (Inf Sci), MSc (Ed Res), PhD, MRPharmS
Dr Karen Pilkington is Senior Research Fellow in the Department of Herbal Medicine and Nutritional Therapy at the University of Westminster in the UK. She originally qualified as a pharmacist and worked in clinical and medicines information roles in the NHS for a number of years. During this time she also trained in information science and established a national specialist medicines information centre. She then became involved in drug usage review and development of clinical guidelines. In 1996, she was appointed Evidence Based Practice Adviser for a health district, an innovative post aimed at improving implementation of evidence into practice. She has continued her work in information and evidence-based practice. In 2003, she joined the university to manage a 4-year UK Department of Health-funded project to review the evidence on complementary therapies in a range of health conditions. A series of published papers, conference presentations and an online database (www.rccm.org.uk/cameol) were the result of this work. Her research continues to focus on methods for producing systematic reviews, assessing evidence on complementary therapies and self-care, and online information resources. In 2005, she was involved in establishing the National Library for Health Complementary and Alternative Medicine Specialist Library and has been instrumental in the development of NHS Evidence – complementary and alternative medicine (www.library.nhs.uk/cam). She co-founded the International Collaboration on Complementary Therapy Resources in 2007, collaboration between information services in Australia, Denmark, Germany, Norway, UK and the USA. She is also Scientific Board member and adviser on information and transparency issues for the European Information Centre on Complementary and Alternative Medicine (EICCAM, www.eiccam.eu).

Dr rer.nat. Mag.pharm. Frederike Zechmeister-Machhart
Dr Friederike Zechmeister-Machhart studied Pharmacy at the University of Vienna and got her Master degree in 1986. After her practical year in a pharmacy she continued her studies with her thesis in pharmaceutical chemistry. In 1993 she was awarded a doctorate of natural science also from the University of Vienna. Since 1993 she is serving in the Austrian Federal Ministry of Health, where she was extensively involved in pharmacovigilance issues. In 2006 she joined the unit responsible for affairs of traditional medicine.

In April 2007 she presented the first proposal on the project “Impact of non-European traditional therapies (e.g. TCM) on pharmaceutical practice” in the former Committee of Experts on Pharmaceutical Questions of the Council of Europe.
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