



CAM 2020

The contribution of
Complementary
and Alternative Medicine
to sustainable
healthcare in Europe



EUROCAM
C/O IVAA OFFICE
194 RUE DU TRÔNE
1050 BRUSSELS
BELGIUM
EMAIL: INFO@CAM-EUROPE.EU
WEBSITE: WWW.CAM-EUROPE.EU

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EUROCAM 2014



This booklet, provided by EUROCAM, an association of European CAM organisations including patients, doctors and practitioners, provides information about Complementary and Alternative Medicine (CAM) scoping its current practice and availability as well as its potential future role across the European Union (EU). In addition, it highlights a number of priority policy action areas to enable CAM to fulfil its significant potential to contribute to the healthcare of citizens throughout the EU.

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Executive Summary

It is a remarkable fact that complementary and alternative medicine (CAM) is now used by one out of two EU citizens.¹ Throughout the European Union people are evidently seeking more natural and gentle methods of healing and increasingly favouring the provision of CAM within existing healthcare systems. This report describes the characteristic features of CAM, reviewing its holistic and individualised approach, its ability to harness a person's innate healing capacity, its focus on salutogenesis² and its emphasis on the therapeutic relationship as well as on prevention, self-care, health literacy and patient empowerment. In the European Union CAM is practised by approximately 145,000 doctors³ dually trained in conventional medicine and a particular CAM modality and around 160,000 trained CAM practitioners (with or without statutory regulation) practising various CAM modalities⁴. This means that there are about 65 CAM providers (30 dual-trained doctors and 35 CAM practitioners) per 100,000 inhabitants compared to the some 475,000 general practitioners (GPs) working in the EU which equates to about 95 GPs per 100,000 EU citizens. These figures demonstrate that there is a vast, largely untapped, reserve of CAM healthcare provision available across the EU. This is a resource that citizens wish to see fully developed and utilised.⁵

Although many Europeans use CAM, there is a huge diversity in its regulation across the EU determining who can practise CAM, what qualifications are required and how services are offered and financed. This patchy provision means that citizens experience practical and attitudinal barriers that limit their access to and use of CAM. To redress these inequalities, it is evident that a pan-European process to instigate an appropriate regulation of providers of CAM throughout the EU should be initiated as soon as possible. This process should take into account the full extent of the scope of CAM modalities across the healthcare spectrum from general health maintenance and education to CAM treatments of specific illnesses. This process should run in parallel with practical measures taken to integrate CAM modalities into the healthcare systems of each and every Member State, a requirement recommended by the World Health Organization (WHO).⁶

The availability of CAM products in the EU, including homeopathic, anthroposophic, herbal and Asian medicinal products, is increasingly being threatened by unharmonised, onerous EU requirements and national regulations that are leading to prohibitive costs for manufacturers or effectively removing traditional medicines from the market altogether. The reduction of the availability of these

1 - www.cordis.europa.eu/news/rcn/35388_en.html. Accessed 23/8/14

2 - Salutogenesis is a term that describes an approach focusing on factors that support human health and well-being, rather than on factors that cause disease

3 - Von Ammon K et al (2012). Health Technology Assessment (HTA) and a map of CAM provision in the EU. Final Report of CAMbrella Work Package 5. Available at https://phaidra.univie.ac.at/detail_object/0:300096

4 - Ibid.

5 - Nissen N et al (2012). Citizens' needs and attitudes towards CAM. Final Report of CAMbrella Work Package 3 – see conclusions 'Citizens' demand and support for CAM and CAM provision in public healthcare Systems'; page 46. Available at https://phaidra.univie.ac.at/detail_object/0:291585. Accessed 19/8/14

6 - WHO (2013) Traditional Medicine Strategy: 2014-2023, WHO Press, Geneva, Switzerland, ISBN 978 92 4 150609 0. Approved at the 67th session of the World Health Assembly of 24 May 2014 (WHA 67.18).

CAM products thwarts the growing demand of European citizens for more natural, health enhancing, low-risk medicinal products and food supplements. It also drives people to purchase unregulated products over the internet which is inherently dangerous. It is essential to reduce overly formalistic and economically prohibitive burdens in the creation of registration dossiers for CAM medicinal and food status products.

The CAMbrella report confirms that European research in the field of CAM is limited and that there is almost no significant investment by any EU Member State in CAM research. The pitiful level of public investment in CAM research in Europe stands in stark contrast to relatively large investments in Australia, Asia and North America. It is essential to include further CAM research in national health research strategies and especially in the EU research programme Horizon 2020.



Introduction

Today's European citizens are increasingly taking responsibility for their healthcare.⁷ The growing use of Complementary and Alternative Medicine (CAM) is a case in point. CAM provision generally lies outside of mainstream medicine but CAM is now used by one out of two EU citizens and is similarly widely accessed in other parts of the world where biomedicine is currently the dominant system of medicine.^{8,9} Citizens are increasingly opting for the therapeutic approach they consider most suited to maintain good health and to prevent or treat illness, irrespective of whether delivered by biomedicine (conventional Western medicine) or CAM. As Europe faces a growing number of challenges in the area of healthcare (e.g. an ageing population, antimicrobial resistance, chronic diseases, mental health problems, rising healthcare costs etc.), it is essential that CAM becomes fully integrated into the healthcare provision of EU Member States.

In view of these health challenges, the Directorate-General for Research and Innovation (a Directorate-General of the European Commission) recently funded a 3-year European survey of CAM, the CAMbrella Project 2010 - 2012. CAMbrella was tasked with reviewing CAM provision in Europe and coming forward with recommendations as to its viability and place within the established EU healthcare system. The findings of the CAMbrella Project were published on line in April 2013.¹⁰ The 'CAMbrella-Roadmap' presents the findings of the eight work packages of this project.¹¹

Whilst acknowledging the widespread use of CAM by European citizens, CAMbrella researchers noted the heterogenic nature of CAM modalities that hindered the assessment of their efficacy, further complicated by a lack of validated data about CAM treatments. CAMbrella also noted significant scientific scepticism regarding the efficacy of CAM as well as the lack of agreed standards of CAM (e.g. its definition, training and education, legal status and regulatory provisions etc.). The CAMbrella report highlighted the lack of integration of CAM into national public health systems and the inadequate research facilities available to CAM.



7 - Pendleton D, Schofield T, Tate P & Havelock P (1984). *The Consultation: An Approach to Learning and Teaching*: Oxford: OUP.

8 - Nissen N et al (2012). Citizens' needs and attitudes towards CAM. *Final Report of CAMbrella Work Package 3*. Available at https://phaidra.univie.ac.at/detail_object/0:291585. Accessed 19/8/14

9 - WHO traditional medicine strategy: 2014-2023. World Health Organization, 2013. ISBN 978 92 4 150609 0

10 - www.cambrella.eu/home.php?il=203&l=deu. Accessed 20/04/14.

11 - The 8 work packages: (1) Terminology and definition of CAM methods (2) Legal status and Regulations, (3) Needs and attitudes of citizens, (4) CAM use- the patients' perspective, (5) Health Technology Assessment (HTA) and a map of CAM provision in the EU, (6) The global perspective, (7) The Roadmap for CAM research in Europe, (8) Communication and dissemination. Available at www.cambrella.eu/home.php?il=203&l=deu. Accessed 20/04/14.



The World Health Assembly - the supreme decision-making body of the World Health Organization WHO - by its resolutions WHA62.13 and WHA67.18¹² urged Member States, inter alia:

- to integrate traditional medicine (TM) and CAM within national healthcare systems by developing and implementing national TM policies and programmes.
- to promote the safety, efficacy and quality of TM/CAM by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards.
- to establish systems for the qualification, accreditation or licensing of TM/CAM practitioners
- to increase the availability and affordability of TM/CAM.

We call on the European health policy decision makers as part of their responsibility to provide satisfactory and cost-effective healthcare for citizens to take note of the resolutions of the World Health Assembly and the findings and recommendations of the CAMbrella Project and to take steps to implement them as soon as possible. In particular CAM therapies can play a significant role in the delivery of primary healthcare which is facing a burgeoning crisis as demand increases at the same time as modern biomedicine becomes ever more costly to deliver. Here CAM has much to offer.

¹² - www.who.int/medicines/areas/traditional/trm_assembly_doc/en/. Accessed 23/8/14.

I

What is Complementary and Alternative Medicine?

I REBIRTH OF NATURAL HEALING METHODS: CAM

In recent years, several definitions of CAM have been suggested. The CAMbrella Project recently defined CAM in Europe as follows: ‘CAM, as utilised by European citizens, represents a variety of different medical systems and therapies based on the knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose, relieve or treat physical and mental illnesses. CAM therapies are mainly used outside conventional health care, but in many countries some therapies are being adopted or adapted by conventional healthcare.’¹³

CAM has roots going back thousands of years to European healing traditions as well as other traditional medicine systems such as those of traditional Chinese medicine, Indian (Ayurvedic) medicine and other similar healing traditions all over the world. These traditional medicine systems display a common holistic approach, founded upon the assumption that wellbeing is intrinsically linked to the integration and balance of the whole person-body, mind, and spirit in harmony with the environment and prevailing culture.

The shift from traditional to modern societies led to the development of a scientific, rational mode understanding health and illness now termed biomedicine.¹⁴ The germ theory of disease and medical advances of the 19th and 20th centuries saw the widespread use of vaccines and the discovery of highly effective antibiotics. Chemists learned to synthesise active plant components in laboratories to produce standardised and readily available, mass-produced drugs. Alongside the introduction of antibiotics, surgical techniques were improved and modern medicine accomplished extraordinary technical achievements. By the late 1950’s, people were becoming accustomed to taking a pill for every ill. Medicine focused on treating individual symptoms and diseases rather than addressing predisposing causes and the needs of the whole person such as diet, lifestyle, and a healthy environment.

But this reliance on a quick fix is changing. Since the latter half of the 20th century, there has been increasing public disquiet with Western science and technology in medicine. Instead of relying solely on biomedicine, citizens are increasingly seeking for alternative and holistic methods of healing. There is clearly a renaissance of natural healing methods in today’s society.

13 - Von Ammon K et al (2012). Health Technology Assessment (HTA) and a map of CAM provision in the EU. Final Report of CAMbrella Work Package 5. Available at https://phaidra.univie.ac.at/detail_object/o:300096

14 - Quirke V, Gaudillière JP (2008). The era of biomedicine: science, medicine, and public health in Britain and France after the Second World War. *Medical History*, 52(4):441-452.

2 EUROPEAN CITIZENS' ATTITUDES TOWARDS CAM

In its Work Package 4, CAMbrella reported 'The reasons people use CAM were reported in 18 studies and were commonly dissatisfaction with orthodox medicine and beliefs in a natural approach which mirrors evidence from other studies.'¹⁵

The motivations revealed by these studies¹⁶ generally fall into two main categories: reasons that highlight the perceived positive aspects of CAM, – so-called 'pull' factors and reasons that focus on the perceived negative aspects of conventional medicine, – or 'push' factors.

The more often cited 'pull' motivations are a desire to take a more proactive role in the caring for one's own health. A partnership in healthcare is sought in which the wellbeing and healthcare needs of individual patients are fully acknowledged and met in the clinical consultation which is reasserted as the central act of medicine.¹⁷ Citizens expect and value aspects of treatment which provide empowerment and a more holistic view of health and healing that goes beyond simply managing symptoms. For this reason they are open to the principles of CAM.

Patients value an approach that encourages their personal autonomy permitting them to participate in the clinical setting as equal partners in decision-making regarding their healthcare. They wish to consult caring and compassionate healthcare professionals who see and understand them as whole human beings.

The most common 'push' motivations reported by CAM consumers are dissatisfaction with aspects of conventional medicine, including unpleasant and at times dangerous side effects, ineffective treatment (e.g. in the case of chronic degenerative diseases), negative aspects of the doctor/practitioner-patient relationship perceived to be 'top down' rather than collaborative and an undue focus on symptomology to the detriment of a holistic overview of health and disease - all this frequently compounded by consultation time constraints.

Citizens want the freedom to choose their own therapies, their doctors and/or practitioners, compatible with their needs, values, ethics, world-view, spiritual philosophy or their perception of the meaning of health and illness. In contrast to conventional medicine, CAM therapies usually highlight the central role of the patient in regaining and maintaining full health and therefore offer an extra dimension to the healing process. Access to various CAM modalities has been made significantly easier with the revolution in information technology, enabling easy access to reputable sources of CAM information on the internet.

15 - Eardley S et al (2012). CAM use in Europe – The patients' perspective. Part I: A systematic literature review of CAM prevalence in the EU. Cambrella Work Package 4, Available at https://phaidra.univie.ac.at/detail_object/0:292161. Accessed 24/8/14.

16 - Furnham A (2004). The psychology of complementary and alternative medicine. *Health Psychology Update*, 13:2-12
Bishop F, Yardley L, Lewith J (2004). Associations and explanations: Who uses complementary medicine and why? *Health Psychology Update*, 13:12-20

17 - Pendleton D, Schofield T, Tate P & Havelock P; *The Consultation: An Approach to Learning and Teaching*: Oxford: OUP. 1984

According to the CAMbrella report, current scientific literature clearly demonstrates that citizens across a number of EU countries increasingly favour CAM provision within the current healthcare systems.¹⁸ However, citizens experience practical and attitudinal barriers that limit their access to and use of CAM. These barriers include (1) practical barriers to CAM, such as its cost and lack of availability of CAM provision, (2) critical attitudes of conventional healthcare professionals to CAM, (3) lack of information and knowledge about CAM and (4) legal constraints to accessing CAM and CAM products, and (5) an exaggerated projection of the risks of CAM in contrast to the often severe side effects caused by conventional medical treatments.^{19, 20}

The importance of increasing research into CAM as a way of supporting the availability of CAM is underlined by citizens and health professionals alike.

Despite the current major differences in the status of CAM between the individual EU Member States the primary objective must be to guarantee patients equitable access to the treatment of their choice, with appropriate guarantees. This is in line with the European Charter of Patients' Rights,²¹ which lists fourteen patients' rights, including the right of access to the health services that answer the individual patient's health needs, the right to information, the right to personalised treatment and the right to choose freely from among different treatment procedures and providers.



18 - Nissen N et al (2012). Citizens' needs and attitudes towards CAM. *Final Report of CAMbrella Work Package 3*. Available at https://phaidra.univie.ac.at/detail_object/0:291585. Accessed 23/8/14

19 - www.amednews.com/article/20110613/profession/306139944/2

20 - <http://antidote-europe.org/en/adverse-drug-reactions-kill-197000-europeans-annually/>

21 - www.activecitizenship.net/patients-rights/materials.html. Accessed 08/05/14.

3 KEY-CHARACTERISTICS OF CAM

A number of key elements are characteristic of the CAM approach to healing. They include:

a HOLISTIC APPROACH

Most Complementary and Alternative Medicine practices are based on a holistic, or ‘whole person’ approach, i.e. how the physical, mental, emotional, and spiritual elements of an individual are interconnected to maintain or regain wellness and health. Holistic approaches focus on the whole individual person rather than just on the illness or a diseased part of the body. They fully involve the patient in the diagnosis and management of his/her illness. Many aspects of a patient’s life may influence a health problem and understanding the ‘whole individual environment’ helps to develop a successful treatment plan. The aim of holistic therapy is to restore harmony of body, mind and spirit.

b HEALTH AS A DYNAMIC RATHER THAN STATIC STATE

Homeostasis, as currently defined, is a self-regulating process by which biological systems maintain stability while adjusting to changing conditions. This concept explains how an organism can maintain more or less constant internal conditions that allow it to survive in the face of a changing and often hostile external environment. When confronted with physiological and mental/emotional stress, a healthy organism is able to mount a protective response, to reduce the potential for harm, and restore an (adapted) equilibrium. If this coping strategy is not successful, illness may result.

This perspective on health and disease is a central tenet of the CAM approach and has lately gained acclaim in a proposal in a mainstream medical journal for a new definition of health as ‘The ability to adapt and self manage in the face of social, physical, and emotional challenges.’²² Rather than health being defined solely as the absence of disease, this dynamic definition focuses on resilience or the capacity to cope which maintains and restores a person’s integrity, equilibrium, and sense of wellbeing.

²² -Huber M et al (2011). How should we define health? *British Medical Journal*, 343:d4163



c ASSISTING THE PERSON'S INNATE HEALING CAPACITY

Human beings are considered as whole, adaptable living systems whose innate constitutional vitality and resistance to disease can be stimulated, supported and strengthened to maintain or regain health. CAM therapies are mainly directed towards reinforcing the resilience, resistance and immune status of the individual concerned thereby reducing the susceptibility to illness and disease as well as addressing any already existing disease process. As such CAM approaches are not limited to simply addressing certain diseases but are universally applicable to patients suffering from all kinds of diseases. Such treatment can be used complementary to conventional medical intervention that is more disease focused.

d INDIVIDUALISED HEALTHCARE AND TREATMENT

CAM therapies vary to suit individual needs instead of being used to treat specific diseases regardless of the individual who is suffering; the focus is on treating the person rather than the condition. Taking account of the patient's constitutional nature and social context as well as the individual response to any affliction enables the doctor/practitioner to adjust and individualise the treatment strategy throughout a course of treatment for optimum effect. A more individualised approach has lately also been acknowledged in mainstream medicine and has become known as 'personalised medicine', which however more narrowly refers to molecular biologic specifications in individuals rather than to a response to individual patient needs as is understood in the concept of person-centred medicine.

e SALUTOGENESIS

Salutogenesis is a term coined by Aaron Antonovsky, a professor of medical sociology. The term describes an approach focusing on factors that support human health and wellbeing, rather than on factors that cause disease. More specifically, the 'salutogenic model' is concerned with the relationship between health, stress, and coping.²³ Salutogenesis explores the reasons why some people stay healthy in the face of hazardous influences whilst others, faced with similar pathogenic factors or other difficulties, fall ill. Thus the ultimate objective of health promotion is to highlight and facilitate the essential prerequisites for maintaining health. Whilst this approach is only applied in a limited fashion, if at all, within biomedical practice²⁴, it is central to the CAM perspective.

23 - Salutogenesis rejects the traditional medical-model dichotomy separating health and illness. Instead it sees the relationship as a continuous variable, the 'health-ease versus disease continuum'. See further: Lindström B et al (2005) Salutogenesis. *Journal of Epidemiology and Community Health*, 59:440-442

24 - Alonso Y (2004). The biopsychosocial model in medical research: the evolution of the health concept over the last two decades. *Patient Education and Counselling*, 53:239-244

f THERAPEUTIC RELATIONSHIP

A positive functioning partnership between the patient and the healthcare professional engages the patient's innate healing capacity and provides motivation to make healthy lifestyle changes. Such a positive therapeutic relationship should not be dismissed as a 'placebo effect' or a 'good bedside manner'. In their encounter with CAM providers, citizens particularly value the following:

- Empathetic communication in consultations with more time available than in biomedical encounters.
- Involvement in their own care through participation in decision-making about their treatment options and the provision of self-help strategies.
- Whole person approach and person-centred healthcare.
- Explanatory frameworks within which to explore health and illness, which are frequently congruent with citizens' own ideas about health and illness.²⁵

Patients report a high satisfaction rating from this kind of encounter.²⁶



g PREVENTION, SELF-CARE, HEALTH LITERACY AND PATIENT EMPOWERMENT

Staying healthy and preventing disease requires the development of personal responsibility and involvement. The concept of self-care requires a conscious focus on and understanding of one's physical, mental and emotional state and the ability to take corrective action when necessary. Helping patients to develop sufficient levels of self-awareness and the know-how required to change unhealthy patterns of behaviour to improve their health is remarkably empowering for the patient. In the first instance, this will enable a person to self-correct a relatively minor health problem. If the condition is more serious it may be necessary to consult a healthcare professional who can work with the patient to take the steps required to recovery. In this way, the patient is not a passive participant; the patient and healthcare professional cooperate as partners.

25 - Nissen N et al (2012). Citizens' needs and attitudes towards CAM. Final Report of CAMbrella Work Package 3. https://phaidra.univie.ac.at/detail_object/0:264407. Accessed 20/04/14

26 - Ibid.



4 INTEGRATED HEALTHCARE

Integrated Healthcare is a relatively new term that emphasizes the combination of CAM and biomedicine (conventional medicine). It emphasises a collaborative approach to patient care among practitioners of different disciplines, and the practice of conventional, complementary, and alternative healthcare that is evidence-based.

In the USA this amalgamation of CAM and conventional medicine is known as Integrative Medicine. In the USA the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM)²⁷ includes 57 highly esteemed academic medical centres (amounting to 20% of all US academic medical centres). Among them are Harvard Medical School, Yale University, Stanford University, Mayo Clinic, Johns Hopkins University, etc.

According to CAHCIM Integrative Medicine aims to ‘help transform medicine and healthcare through rigorous scientific studies, new models of clinical care, and innovative educational programs that integrate biomedicine, the complexity of human beings, the intrinsic nature of healing and the rich diversity of therapeutic systems’.²⁸

27 - www.imconsortium.org. Accessed 20/04/14.

28 - Kligler B et al. (2004). Core competencies in integrative medicine for medical school curricula: a proposal. *Academic Medicine*, 79(6):521-531.

II

CAM in practice

I HOW IS CAM DELIVERED TO EU CITIZENS?

Over the years many different models of CAM delivery have developed. They range from the single doctor or practitioner in private practice, through multi-disciplinary CAM clinics where joint approaches to patient care involving cross-referrals take place, to CAM doctors and practitioners working collaboratively in conventional healthcare settings such as GP and specialist practices, and (university) hospital-based in-patient and out-patient clinics.²⁹

In the European Union there are approximately 145,000 dual-trained doctors, i.e. trained in conventional medicine and a particular CAM modality.³⁰ CAM is also increasingly practised by dentists and veterinarians. CAM modalities include acupuncture, anthroposophic medicine, ayurvedic medicine, herbal medicine/phytotherapy, homeopathy, naturopathy, osteopathy, chiropractic and traditional Chinese or Tibetan medicine among others. They all may be integrated into patient care within the context of general medical practice, conventional specialist practice or full-time CAM practice. CAM treatment is provided within a broad scope, which includes an awareness of the need for conventional medical diagnosis, prognosis and treatments.



29 - some examples: Humlegaarden (Humblebaek, Denmark); Vidarkliniken (Färna, Sweden); Bristol Cancer Help Center (Bristol, UK), Royal London Hospital for Integrated Medicine (London, UK); Gemeinschaftskrankenhaus Herdecke, (Herdecke Germany), Gemeinschaftskrankenhaus Hafelhöhe (Berlin, Germany), Filderklinik (Stuttgart, Germany), Paracelsus Krankenhaus (Öschelbronn, Germany), Hufeland Clinic (Bad Mergentheim, Germany); Klinik für Komplementäre und Integrative Medizin in der Zentral-Klinik Essen (Essen, Germany), Lukas Klinik (Arllesheim, Switzerland), Ita-Wegman Klinik, (Arllesheim, Switzerland).

30 - Von Ammon K et al (2012). Health Technology Assessment (HTA) and a map of CAM provision in the EU. Final Report of CAMbrella Work Package 5. https://phaidra.univie.ac.at/detail_object/0:300096

In addition to the approximately 145,000 physicians practising CAM therapies, there are in the order of 160,000 non-doctor CAM practitioners³¹ practising CAM modalities such as those just mentioned, as well as other CAM therapies, such as aromatherapy, kinesiology, massage, reflexology, shiatsu, yoga, qigong, etc. CAM offers a whole person approach to health, each CAM therapy seeking to help the patient according to its distinct diagnostic and treatment methods. CAM treatments can be provided on a stand-alone basis and/or complementary to conventional medicine approaches. These modalities are delivered mostly in private practice. Increasingly CAM practitioners regularly collaborate with conventional medical practitioners.

2 HOW IS CAM PRACTISED?

An important part of the CAM health professional's task is diagnostic work: working in close collaboration with the patient to track down any health imbalance and its causative factors. In addition to any specific treatment that may be given, advice is given on adaptation of lifestyle, diet and behaviour, suggesting the use of appropriate stress-reduction techniques and exercise. The patient is an active participant in this healing process; his/her commitment to change calls on the innate regenerative potential of every individual. Since each person is unique, treatment programmes are generally tailored to each individual's requirements.

The holistic approach of CAM does not replace the biomedical concept of disease. Rather, it includes and goes beyond this concept considering all that contributes to good and bad health (i.e. a wide spectrum of predisposing factors) that the average conventional medical doctor often has neither the time, nor always the training to explore. This may include detailed consideration of dietary issues and present and past stress factors that may respond to the adoption of mindfulness practice, designed to modulate the stress response and improve unhealthy behaviours.



3 CAM TRAINING AND EDUCATION

Most training in CAM in Europe is designed and delivered by non-profit associations and institutions and by private teaching / training centres for each CAM modality. In some Member States CAM therapies are now taught at universities to Bachelor of Honours level. Curriculum content, knowledge and skill levels, and examination procedures are generally overseen by the individual professional bodies of each CAM modality based on defined standards of training and particular systems of accreditation, registration and on-going CPD/CME (Continuing Professional Development, Continuing Medical Education) of CAM health professionals. There is currently no overall European legal framework for training in CAM modalities.

³¹ - Ibid.



CAM training and education for medical doctors is mostly provided through non-profit associations and privately run schools and courses, but also at a number of European universities as postgraduate training courses. Professorial chairs of CAM exist in at least 8 EU Member States and in some Member States there are also chairs in a specific CAM modality. Familiarisation courses about CAM modalities are provided in the medical undergraduate curricula in most EU Member States; this study is optional in most countries, obligatory in some.

The CAM professions are working with both health and education authorities on a national level to institute state-recognised training courses and accreditation. A much faster take up of these initiatives and progress towards European level awards and mutual recognition is highly desirable.

III

Implementing health policies for CAM



CAM represents an important part of healthcare delivery and provision in Europe. It is a rapidly growing part of the economy, used by significant numbers of EU citizens. CAM should be included in EU strategic approaches to health promotion and prevention but it is currently largely ignored by those who make EU health policy. CAM can significantly contribute to answer the needs of such European priorities as improving public health, enabling healthy ageing, providing affordable health systems, reducing antimicrobial resistance and redressing health inequalities.

1 CAM AND PATIENT EMPOWERMENT

Personal responsibility for one's own health is a vital aspect in the prevention of illness. CAM has always been a strong proponent of:

- a more prominent role for the patient in the healthcare system
- the right of patients to assume responsibility for their own healthcare
- encouraging and enabling citizens to become more knowledgeable about health related subjects.

Health competence is a term now used to describe the knowledge, skills and development of the right attitudes to live a healthy life. Health competence includes knowledge of and engagement in healthy eating, exercise, maintaining a healthy environment, healthy relaxation and a healthy work-life balance. The furtherance of health competence is a key feature of CAM: CAM practitioners are able to make significant contributions in the field of health competence and their expertise should be utilised by those making health policy.

2 CAM AND PERSONALISED MEDICINE

'Pharmaceutical development has led to thousands of medicines available worldwide, but many medicines are not as effective as expected in all patients, and some patients may suffer from serious adverse reactions. The reason for this is that therapies traditionally have been developed, and prescribed, using an 'average patient' approach that does not take into account patients' 'molecular make-up', a factor that, together with environmental and lifestyle factors, determines susceptibility to disease, the course of disease, and response to treatment.'³²

Personalised medicine is a medical approach which is tailored to the patient or a group of patients – whether for prevention, prognosis or treatment. In other words, it moves away from the common 'one size fits all' medical model. This approach is now being financially supported by the European Commission.

³² - Commission Staff Working Document SWD (2013) 436 final - Brussels, 25.10.2013. www.ec.europa.eu/health/files/latest_news/2013-10_personalised_medicine_en.pdf. Accessed 20/04/14.

CAM is personalised medicine ‘avant la lettre’. Knowing the patient’s constitutional nature and temperament enables the CAM health professional to adjust and individualise the treatment strategy accordingly for optimum efficacy.

3 CAM AND SAFETY

CAM is generally considered safe and this is a major reason for its popularity. Individual risk levels may however vary from one CAM therapy to another but adverse effects noted in research literature are rarely of a serious nature. Unregulated herbal medicines may present a risk of adverse effects and whilst there is a possibility for interaction with conventional medicines, in the hands of properly trained herbalists such risks are minimal.³³ Herbal medicinal products can be acceptably safe if used properly and under the guidance of an appropriately trained professional.³⁴

EU statistics reveal that 8-12% of patients admitted to hospital suffer adverse events from conventional medicine while receiving care and at least 198,000 patients die each year from medical errors whether from adverse drug reactions, antibiotic resistant micro-organisms, wrong diagnosis or surgical error.^{35, 36} The costs of dealing with the consequences of these events run into billions of euros annually. The good safety profile of CAM³⁷ is another cogent reason for CAM to be integrated into health systems, thereby reducing some of the more high-risk interventions which inevitably pose more risks to patient safety.

Professional CAM associations consider user safety as paramount and have therefore established guidelines for training, certification and practice, as well as requiring professional insurance and operating robust codes of ethics and complaints procedures.

4 CAM AS INNOVATIVE AND EFFECTIVE TREATMENT

Over the last few decades an increasing amount of research has been published on the effectiveness of CAM modalities. In fact, the Cochrane Collaboration³⁸, an international effort to develop an evidence base for a wide variety of medical therapies, both conventional and CAM, lists more than 4,000 randomized trials for various CAM therapies in its electronic library. Furthermore, a number of Cochrane Collaboration systematic reviews of this worldwide research literature have identified the potential benefits of CAM and related approaches and products for a number of chronic conditions. At the Cochrane Summaries website over 600 Cochrane reviews³⁹ related to CAM can be found. Any individual scientific paper related to CAM is accessible at ‘CAM on PubMed’⁴⁰, a subset of PubMed at the US National Library of Medicine.

33 - Bensoussan A, Myers P (1996). *Towards a Safer Choice: The Practice of traditional Chinese medicine in Australia*, Victorian Dept of Services NSW DoH & Queensland DoH, University of Western Sidney MacArthur.

34 - www.who.int/medicines/publications/traditional/trm_strategy14_23/en. Accessed 16/02/2014.

35 - www.ec.europa.eu/health/patient_safety/policy/index_en.htm. Accessed 20/04/14.

36 - www.encepp.eu/publications/documents/NewLegislationonPharmacovigilance.pdf. Accessed 29/5/14.

37 - Australasian Integrative Medicine Association (2014). Best practice for Integrative Medicine in Australian medical practice. *Advances in Integrative Medicine*, [www.aimedjournal.com/article/S2212-9626\(13\)00046-1/abstract](http://www.aimedjournal.com/article/S2212-9626(13)00046-1/abstract)

38 - www.cochrane.org. Accessed 29/5/14.

39 - summaries.cochrane.org/search/site?f%5B%5D=im_field_terms_archive_topics%3A948&f%5B%5D=im_field_stage%3A3. Accessed 08/05/14.

40 - nccam.nih.gov/research/camonpubmed. Accessed 19/8/14.

A review of 145 Cochrane reviews of RCTs in the field of CAM using the 2004 database revealed that 24.8% concluded with a positive effect or possibly positive effect (12.4%), 4.8% concluded that there was no effect, 0.69% concluded that there was a harmful effect, and 56.6% concluded that there was insufficient evidence.⁴¹ These figures have similarities to data obtained from an analysis of 1016 systematic reviews of RCTs in medicine in general using the 2004 database: 44.4% of the reviews concluded that the interventions studied were likely to be beneficial (positive), 7% concluded that the interventions were likely to be harmful (negative), and 47.8% reported that the evidence did not support either benefit or harm (non-conclusive).⁴²

	(POSSIBLE) POSITIVE EFFECT	LIKELY TO HAVE NO EFFECT	LIKELY TO BE HARMFUL	INSUFFICIENT EVIDENCE
CAM	37.2%	4.8%	0.69%	56.6%
MEDICINE IN GENERAL	44.4%	0.98%	7%	47.8%

41 - Committee on the Use of Complementary and Alternative Medicine by the American Public (2005). 5 State of Emerging Evidence on CAM: Cochrane Review Evidence for CAM. *Complementary and Alternative Medicine in the United States*. Washington DC: The National Academies Press. pp. 135–136. ISBN 978-0-309-09270-8.

42 - El Dib RP, Atallah AN, Andriolo RB (2007). Mapping the Cochrane evidence for decision making in health care. *Journal of Evaluation in Clinical Practice*, 13:689–692.

43 - Weidenhammer W et al (2007) Acupuncture for chronic pain within the research program of 10 German Health Insurance Funds-basic results from an observational study. *Complementary Therapies in Medicine*, 15:238-246. Spence D et al (2005) Homeopathic Treatment for Chronic Disease: A 6-Year, University-Hospital Outpatient Observational Study. *Journal of Alternative and Complementary Medicine*, 11:793-798.

44 - Long AF (2009). The potential of complementary and alternative medicine in promoting well-being and critical health literacy: a prospective, observational study of shiatsu. *BMC Complementary and Alternative Medicine*, 9:19 Hill FJ (2003) Complementary and alternative medicine: the next generation of health promotion? *Health Promotion International*, 18:265-272.

Several long-term outcome studies have shown that CAM therapies can be at least as effective as conventional care with fewer side effects and higher patient satisfaction. Other research studies have shown that three quarters of chronically ill patients undergoing CAM treatment described themselves as ‘moderately better’ or ‘much better’.⁴³ CAM modalities may be particularly helpful in motivating and supporting healthy lifestyle change thereby helping people to maintain health and prevent illness.⁴⁴



5 CAM AND COST-EFFECTIVE HEALTHCARE PROVISION

According to the EU Commission⁴⁵ and the Economic Policy Committee⁴⁶ cost-effective provision and use of health services is one of the areas where structural reforms and efficiency gains could improve the sustainability of health systems.

Supporting good health and prevention of illness is now recognised as having the greatest cost-effective and health outcome potential both for citizens and health systems. Good health is a value in itself and promoting the well-being of its peoples is enshrined in article 3 the Treaty of Lisbon. Good health is now also recognised as an economic driver as well as a cohesive force in families and communities. The strategic aim of the EU Commission ‘Health for Growth’ seeks substantially healthy longevity.⁴⁷

CAM modalities are typically not dependent on complex and expensive technological interventions, instead providing low-cost treatments. In contrast with conventional prescription drugs, homeopathic, herbal and anthroposophic medicines are generic, non-patentable medicinal substances that are produced at relatively low costs. By and large they do not incur any further costs caused by adverse effects.

CAM modalities can often be used as a first option in treating many conditions, sparing the use of more costly biomedical drugs which nevertheless remain as a possible backup. CAM modalities can help to prevent the often long-term dependency on conventional medication and to reduce the enormous burden of mortality and morbidity caused by the adverse effects of conventional biomedical drugs and the ever-increasing resistance to antibiotics.

The use of CAM modalities may therefore offer significant cost savings to public health systems and to the economy more widely. Several research studies have demonstrated that patients who were treated with various CAM modalities used fewer medications, had better health, fewer days off sick, and fewer visits to medical specialists than patients of conventional physicians⁴⁸ all of which can contribute to long-term compound savings in health budgets.

In the last three years the cost-effectiveness of acupuncture according to international benchmarks was recognised for treating headache, low back pain and neck pain⁴⁹, which account for large amounts of absenteeism amongst Europe’s workforce. A recent comprehensive systematic review of economic evaluations of complementary and integrative medicine (CIM) by Herman et al. reviewed the contribution of these therapies to health reform efforts and identified emerging evidence of cost-effectiveness and possible cost savings in at least a few clinical populations.⁵⁰ Economic evaluations demonstrated that patients whose GP had



45 - Commission staff working document “Investing in Health” SWD(2013) 43 final

46 - <http://europa.eu/epc/>.

47 - Proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020. COM(2011) 709 final

48 - Busato A et al (2005). Health status and health care utilisation of patients in complementary and conventional primary care in Switzerland - an observational study. *Family Practice*, doi:10.1093/fampra/cmio78

49 - Witt CM et al (2008) Cost-effectiveness of acupuncture treatment in patients with headache. *Cephalalgia*, 28:334-345
Witt CM et al (2006). Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain. *American Journal of Epidemiology*, 164:487-496.
Willich SN et al (2006). Cost-effectiveness of acupuncture treatment in patients with chronic neck pain. *Pain*, 125:107-113.

taken additional training in a particular CAM therapy had substantially lower healthcare costs and lower mortality rates than GPs without such training.⁵¹ The lower costs result from fewer hospital stays and fewer conventional biomedical drugs. The wider economic savings made through reducing absenteeism by patients or those caring for them are less easy to quantify but are nonetheless implied.

Lifestyle Modification Programs (LMPs) are group-based behaviour modification interventions that support patients at high risk to undertake behaviour change to prevent or delay the onset of developing chronic disease. The ‘Dr Dean Ornish Program for Reversing Heart Disease in the USA’ is a good example of such a programme. It includes improved physical conditioning through low impact aerobic exercise and strength training, relaxation techniques to help cope with and reduce stress, a nutrition plan based on low-fat intake and whole foods and, finally, group support to enable participants to deal with the emotional issues that contribute to or result from heart disease. It can reverse coronary heart disease without drugs or invasive surgical procedures such as arterial bypasses or angioplasty.⁵² This approach costs about \$7,000 (€ 5,500) per patient, which is only a fraction of the costs for cholesterol-lowering, anti-hypertensive and antianginal medications, which may amount to thousands of Euros per year or tens of thousands euros for life, assuming that the patient lives thirty or forty more years. This does not take into account the costs of coronary bypass surgery and angioplasty (also tens of thousands of euros).

50 - Herman PM et al (2012). Are complementary therapies and integrative care cost-effective? A systematic review of economic evaluations. *BMJ Open*;2:e001046

51 - Kooreman P & Baars EW (2012). Patients whose GP knows complementary medicine tend to have lower costs and live longer. *European Journal of Health Economics*, 13: 769-776
 Studer HP & Busato A (2011). Comparison of Swiss Basic Health Insurance Costs of Complementary and Conventional Medicine. *Forschende Komplementärmedizin*, 18:315–320

52 - Ornish D et al (1990). Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. *Lancet*, 336(8708):129-133.
 Ornish D et al (1998). Intensive lifestyle changes for reversal of coronary heart disease. *Journal of the American Medical Association*, 280:2001–2007.



6 CAM AND ANTIMICROBIAL RESISTANCE

Both the WHO and the EU have identified antimicrobial resistance as a major crisis facing the health systems of all countries worldwide. Widespread use of antibiotics in the animal food industry has been a major contributor to the rise in resistance. The pharmaceutical industry is struggling to find new antibiotics to replace the failing older products. The European Centre for Disease Prevention and Control estimates that antimicrobial resistance (AMR) results each year in 25,000 deaths and related costs of over €1.5 billion in healthcare expenses and productivity losses in Europe. In the light of this crisis and in order to reduce the use of antibiotics, there is sufficient evidence and practical experience that some CAM modalities can contribute to the greater efforts needed to encourage healthy lifestyles reducing the need for antibiotic use. In addition, increasing evidence suggests that herbal, anthroposophic and homeopathic medicine can offer effective alternatives to antibiotics. They must therefore be seriously considered and investigated by the EU, both for human health and animal health.

7 CAM AND HEALTHY AGEING

By 2025 about one-third of Europe's population will be 60 years or over and there will be a significant increase in the number of people 80 years and older. European societies need to support healthy people living longer and productive lives. Without a sea change that sees positive measures implemented to support the aims of Healthy Ageing, the burden on care services may become intolerable.

CAM's focus on salutogenesis is inherently geared to supporting healthy active longevity. Surveys show that it is in early middle age that citizens begin to regularly use CAM when awareness about the need to stay healthy and the onset of chronic illness tend to coincide, and when they are seeking methods to take care of their health in a positive and sustainable way.



8 CAM AND PREVENTION

The Organisation for Economic Co-operation and Development (OECD) notes that only 3 % of health budgets are spent on prevention and promotion, leading to calls for a paradigm shift away from treating illness and towards helping individuals to make healthier choices and take greater responsibility for their own health.⁵³ This is an area where CAM professionals can provide added value by supporting their patients to adopt healthy behaviour, a key challenge in tackling lifestyle-related chronic conditions. At the level of primary prevention, CAM modalities can be effective in health promotion, including lifestyle counselling, dietary guidance,

53 - www.oecd.org/health/ministerial/healthychoices.htm



stress reduction techniques, interventions to improve sleep quality, and use of nutritional and herbal supplements for health promotion. At the level of secondary prevention, stress management and nutritional supplementation can reduce risk factors for chronic disease. At the level of tertiary prevention, the full range of CAM modalities supports goals such as pain management, stress relief, disease management, and risk reduction.⁵⁴

9 CAM - ACCESS AND HEALTH INEQUALITIES

Analysis of the relation between health and socio-economic status consistently reveals that better health is enjoyed by those with higher economic status. Similarly, use of CAM is associated with those with higher economic status. Due to the fact, that CAM modalities are not integrated in the public health system, patients have to rely on private funds or private health insurance companies to pay for CAM medicinal products. While a direct relation between these two sets of data remains to be firmly established, the fact that access to the benefits of CAM are currently only available to those who can afford to pay for them and know about them, clearly points to inequality of access to CAM by poorer EU citizens. The different regulatory framework for CAM across the EU further adds to such inequalities, as patients in some Member States have access to more treatment choices than do the populations of other Member States.

CAM can contribute in several ways to reducing health inequalities. Several CAM modalities combine basic health education with treatment of illness. They can be delivered both on an individual basis, in community settings and within formal education. Delivery is personalised with a high motivation capacity leading to the desire for and uptake of personal responsibility for health and to a level of health literacy that can aid the prevention of illness. In addition, the use of cost effective CAM interventions in the treatment of illness frees available resources for other programmes to reduce health inequalities.

10 CAM AND SUSTAINABLE HEALTH SYSTEMS

While the organisational structure and funding mechanisms of health systems varies across Europe, the general reliance on the biomedical model of healthcare with all its associated costs, inefficiencies, inequalities of access and patient dissatisfaction calls for a radically new approach. With increasing costs of the treating of chronic disease, the inexorable increase in costs associated with an ageing population and the demands of ever more expensive medical technologies, there appears little prospect that resources can match demand. Systemic change is required.

54 - Katz, DL & Ali A (2009). Preventive medicine, integrative medicine & the health of the public. IOM Summit on Integrative Medicine and the Health of the Public, USA. www.nap.edu/openbook.php?record_id=12668. Accessed 20/04/14.

CAM offers solutions to these seemingly intractable problems providing health-care delivery based on supported self-responsibility and health literacy that can do much to support health maintenance and the prevention of illness. The CAM model also offers financial sustainability by encouraging disease prevention via less costly interventions that potentially lead to long lasting outcomes of treatment. There is a small but growing amount of evidence to show that the introduction of CAM into primary care can improve morbidity and mortality while reducing healthcare costs.⁵⁵



11 CAM AND EU HEALTH POLICIES - 'INVESTING IN HEALTH'

In the last decade a set of policy orientations for European public health policies has been developed by the EU Commission like 'health in all policies' or the guideline 'Health for Growth'. These strategies aim to integrate European health policies within all other European policies. Due to the financial and economic crisis, the overarching aim of the EU Commission is now to concentrate all political activities of the Union on achieving a better economic performance.

Because it accounts for major outlay of public finances, health policy is a focus of this development. The EU Commission health department, DG SANCO, has therefore suggested concentrating European public health policies on 'Investing in Health' with the objective to invest in sustainable health systems, to focus on health as investment in human capital and to reduce inequalities in health. These general policy objectives suggest substantial changes to the existing health system, improving its cost efficiency through sound innovation, promoting good health and investing in human capital. Finding cost-reductions whilst ensuring the provision of better health for the European workforce are paramount.

55 - Herman PM, Poindexter BL, Witt CM, et al. (2012) Are complementary therapies and integrative care cost-effective? A systematic review of economic evaluations. *BMJ Open*, 2:e001046.



CAM is consistent with the priorities of this EU Health Strategy particularly promoting healthy ageing and supporting innovative health systems. CAM practices inherently promote health literacy and healthy lifestyle habits, and are often used for the management of chronic diseases that are major causes of lost work days like back pain, stress and depression. CAM thus has a role to play in building economic prosperity by enhancing health in the work place and cutting illness-related absences. In fact, CAM is the outstanding major, low-cost innovation available in Europe. It would seem that CAM's time has come as it has the potential to enable public health systems across the EU to attain the goals of the European health policy 'Investing in Health' and thus support sustainable healthcare systems.

IV

Better regulation for the CAM workforce



I THE CURRENT CAM WORKFORCE

As previously mentioned, the CAMbrella report identified approximately 310,000 CAM providers in the European Union, comprising nearly 160,000 non-doctor practitioners and 145,000 doctors.⁵⁶ This suggests up to 65 CAM providers (35 non-medical practitioners and 30 doctors) per 100,000 inhabitants compared to the EU figures for GPs (475,000 MD general practitioners), which equals 95 per 100,000 inhabitants.

Acupuncture is the most provided method for both doctors (80,000) and non-medical practitioners (16,380), followed by homeopathy (45,000 doctors and 5,250 non-medical practitioners), with both disciplines being dominated by doctors.⁵⁷ The use of herbal medicine/phytotherapy is difficult to assess as herbal medicinal products are in use by doctors in several EU Member States (e.g. Germany⁵⁸) and are also used by other CAM practitioners such as naturopaths and practitioners of traditional Chinese medicine and Ayurveda. According to a CAMbrella survey, herbal medicine is the most reported CAM therapy used by patients, variously categorised as medical herbalism, herbal medicine, herbs, herbal products, herbal therapies, herbal remedies, herbal teas and phytotherapy.⁵⁹ Reflexology (24,600) is (by self-declaration) almost exclusively provided by non-medical practitioners. Naturopathy (22,300) is predominately practised by (15,000 mostly German) doctors. Anthroposophic medicine (4,500) and neural therapy⁶⁰ (1,500) are the most provided methods practised exclusively by doctors.⁶¹

2 THE PRESENT CHAOTIC STATUTORY REGULATION OF CAM IN EUROPE

Although many Europeans use CAM, there is a huge diversity of regulation across the EU determining who can practise, what qualifications are required and how services are offered and financed. Some EU Member States have government-administered regulations or laws about the practice of CAM in general, some have sections on CAM included in their health laws, some regulate specific CAM therapies, while many national health systems do not recognise or regulate CAM at all.

There are major obstacles for both medical and non-medical practitioners when crossing borders. While CAM professions in some Member States are tightly regulated, the same professional categories in other countries are totally unregulated. This situation makes it almost impossible to establish professional common ground and cross-border employment or cross-border health provisions for citizens and patients. All this raises serious concerns with regard to the predictability, quality and safety of healthcare delivery across Europe for its citizens.

56 - Von Ammon K et al (2012). Health Technology Assessment (HTA) and a map of CAM provision in the EU. Final Report of CAMbrella Work Package 5. Available at https://phaidra.univie.ac.at/detail_object/o:300096

57 - *ibid.*

58 - Joos S, Glassen K, Musselmann B (2012). Herbal Medicine in Primary Healthcare in Germany: The Patient's Perspective. *Evidence-Based Complementary and Alternative Medicine*, Volume 2012, Article ID 294638.

59 - Eardley S et al (2012). CAM use in Europe – The patients' perspective. Part I: A systematic literature review of CAM prevalence in the EU. Cambrella Work Package 4, Available at https://phaidra.univie.ac.at/detail_object/o:292161. Accessed 24/8/14.

60 - A form of complementary and alternative medicine in which local anaesthetic is injected into certain locations of the body.

61 - Von Ammon K et al. *Op cit.*

The CAM professions are actively seeking regulation appropriate to the range and scope of practice of the different modalities both in the interests of safe and informed access by the public and of the professional development of the modalities. Therefore, a process for the appropriate regulation of providers of CAM across the EU should be initiated. This process should take into account the full extent of the scope of action of CAM modalities across the healthcare spectrum from health maintenance and education to complementary treatment of illness. It would help the integration of CAM modalities in the healthcare systems in Member States, a requirement recommended by the World Health Organization.⁶²



The Directive on the Recognition of Professional Qualifications (Directive 2005/36/EC)⁶³ is an important legal basis for free movement of professionals in Europe. To ensure freedom of establishment and freedom to provide services for providers of CAM, the existing Directive should be amended or, if necessary, new framework regulation should be proposed.

3 FACILITATING CAM PROVISION ACROSS EUROPE

The conclusions and recommendations of the CAMbrella report underline the pressing need of a common regulation of CAM in Europe. Such a regulation should encompass CAM practice and methods, including an operational definition of CAM disciplines and methods as well as transparent systems for training, qualification, accreditation or licensing of CAM providers.

The report recommends that the European Parliament and the Commission take initiatives to secure the application of the principles of freedom of movement of workers, the right of establishment and freedom to provide services as stipulated in the Treaty Establishing the European Community (The Treaty of Rome) and, in particular, to prompt Member States to coordinate the conditions for the exercise of the medical and allied professions. These differences in status currently stand in the way of full harmonisation of the practice of CAM throughout the EU, particularly with regard to the practice of medicine, medical education, reimbursement of treatment costs by social security systems and the establishment of a comprehensive pharmacopoeia that includes a full range of CAM medicinal products. All Community nationals must be guaranteed the right of establishment, by abolishing any current restrictions and being given the means to exercise their profession without restraint.

62 - WHO traditional medicine strategy: 2014-2023. World Health Organization, 2013. ISBN 978 92 4 150609

63 - Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications.

Such a development would be entirely in line with resolutions WHA56.31 (2003), WHA62.13 (2009) and WHA67.28 (2014)⁶⁴ of the WHO World Health Assembly - the supreme decision-making body of WHO -, which urged Member States, inter alia:

- to integrate traditional medicine (TM) and CAM within national healthcare systems by developing and implementing national TM policies and programmes.
- to promote the safety, efficacy and quality of TM/CAM by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards.
- to establish systems for the qualification, accreditation or licensing of TM/CAM practitioners
- to increase the availability and affordability of TM/CAM.



3.1 DOCTORS WITH AN ADDITIONAL QUALIFICATION IN A PARTICULAR CAM MODALITY

Doctors trained in conventional medicine and in one or more CAM modalities, integrate a CAM modality into patient care within the context of general medical practice, conventional specialist practice or concentrate on practising CAM exclusively. CAM treatment is provided within a care plan that includes medical diagnosis, prognosis and treatments.

According to Directive 2005/36/EC⁶⁵ basic medical training and general practitioner training are automatically recognised throughout the EU and some specialist doctors' qualifications are automatically recognised in certain EU countries. However, additional qualifications for doctors practising CAM modalities do not meet the automatic criteria for recognition.

For the time being, a formal specialist doctors' qualification is not viable because the length of the existing specialised training courses is less than 3 years of full-time training as required in Directive 2005/36/EC, and because new medical specialties can only be included if they are common to at least two fifths of the Member States.

Currently, some European doctors' associations have started a procedure, through the European Committee for Standardisation CEN, leading to a European standard setting safety, quality and performance requirements for doctors with an additional qualification in a particular CAM modality. The role of CEN in developing services standards was confirmed by the new EU Regulation on European standardization (Regulation 1025/2012).

64 - www.who.int/medicines/areas/traditional/trm_assembly_doc/en/

65 - Chapter III, Section 2 of Directive 2005/36/EC

In future these additional qualifications may be eligible for the general system for recognition of qualifications (article 10-15 of Directive 2005/36/EC). Such a step could be most helpful in attaining legal recognition of doctors with specific expertise in a particular CAM modality.⁶⁶

3.2 OTHER STATUTORILY REGULATED HEALTH PROFESSIONALS HAVING AN ADDITIONAL QUALIFICATION IN A PARTICULAR CAM MODALITY

Other statutorily regulated health professionals, such as dental practitioners, nurses, physiotherapists and midwives can integrate a CAM modality into their care. Training of these health professionals provides the assurance that ‘they have sufficient understanding of the structure, physiological functions and behaviour of healthy and sick persons, and of the relationship between the state of health and the physical and social environment of the human being’.⁶⁷

Currently, some European associations uniting these health professionals have started a procedure, through the European Committee for Standardisation CEN, leading to a European standard setting safety, quality and performance requirements for health professionals with an additional qualification in a particular CAM modality.

In future these additional qualifications may be eligible for the general system for recognition of qualifications (article 10-15 of Directive 2005/36/EC). Such a step could be most helpful in attaining legal recognition of these health professionals with a specific expertise in a particular CAM modality.

3.3 NON-STATUTORILY REGULATED (NON-MEDICAL) PRACTITIONERS HAVING A QUALIFICATION IN A PARTICULAR CAM MODALITY

Non-medical practitioners who have undertaken education and training in one or more CAM modalities practise a CAM modality as a distinct discipline in itself. They offer a complementary and/or alternative approach to complement medical care for maintaining health and for preventing and treating illness.

The establishment of a regulatory regime for this category of healthcare professionals falls within the competence of individual EU Member States. Most of these health professionals are not statutorily regulated in any EU Member States and therefore not recognised under Directive 2005/36/EC. Some, however, have taken a diploma of post-secondary level according to article 11d or 11e of the Directive.

⁶⁸ Some CAM professions like chiropractic and osteopathy achieved statutory regulation in some EU Member States.

⁶⁶ - The same applies for sports medicine, occupational medicine, preventive and social medicine among others.

⁶⁷ - Chapter III, Sections 3-6 of Directive 2005/36/EC

⁶⁸ - The EU Regulated Professions Database shows that the profession of chiropractor is regulated in 12 European countries, osteopath in 6, acupuncturist in 1, other CAM professions are not (Database accessed January 2014).



Currently, several European CAM practitioners' organisations have established or are establishing a commonly agreed European profile for their profession and some of them have subsequently followed a procedure, through the European Committee for Standardisation CEN or European Leonardo program ECVET, leading to a European standard qualification setting safety, quality and performance requirements for that particular group.

4 THE CROSS-BORDER DIRECTIVE

The Cross-border Healthcare Directive 2011/24/EU is aimed at facilitating access to safe and high-quality cross-border healthcare and cooperation on healthcare between the Member States, whereas at the same time the Member States' rights to organise their own healthcare system stands unchanged. The Directive emphasises the patients' rights to access safe and high-quality treatment and to be reimbursed for it.

However, European CAM practitioners have different levels of training as a basis for their practice, whether they are formally licensed or not and patients have varying expectations of what is available in other Member States depending on experiences from their home country. This heterogeneous situation impacts on CAM patients' rights to access safe treatment and constitutes a challenge to a harmonised national and European revision of the Cross-border Healthcare Directive.

5 CONCLUSION

The future of the CAM health workforce has to be viewed in the context of the general development of the health workforce in Europe. An increasingly ageing European population is putting a strain on EU health systems with growing numbers of chronic diseases and severe disabilities requiring long-term treatment. In order to provide a sustainable workforce within the various EU health systems to meet these needs, it is essential to expand the size and scope of the future health workforce. Such plans should harness the considerable potential of CAM therapy to meet the health needs of European citizens throughout the EU.

There is common agreement that a focus on maintenance of good health is a fundamental key to controlling healthcare costs. In these circumstances, the sustainability of health services requires a policy shift towards health promotion and prevention of illness as well as the adoption of a more cost-effective treatment of illness. As mentioned, there are some 350,000 CAM health professionals available to contribute to this shift in health service provision. CAM professionals are well placed to deliver health education, prevention strategies and longer lasting effective treatment of illness - all contributing to cost-efficient health provision with an emphasis on self-motivated health maintenance .

V

Rethinking the availability of CAM medicinal products

The availability of CAM products in the EU, including homeopathic, anthroposophic, herbal and Asian medicinal products, is increasingly being threatened by unharmonised, onerous requirements and idiosyncratic national regulations that are leading to prohibitive costs for manufacturers. In contrast to prescription drugs, CAM medicinal and food status products are generic, non-patentable substances. The decreasing availability of such CAM products thwarts the growing demand of European citizens for more natural, health enhancing, low-risk medicinal products and food supplements. It also drives people to purchase unregulated products over the internet, which is inherently dangerous.

I HOMEOPATHIC MEDICINAL PRODUCTS

European regulations (Directive 2001/83/EC as amended) allow for the simplified registration of homeopathic preparations, provided they are manufactured according to a procedure defined in the European Pharmacopoeia (EP) or – in cases where the procedure is not yet included in the EP, in a national homeopathic pharmacopoeia such as the German or the French homeopathic pharmacopoeias. The registration procedure is not harmonised: registrations are purely national and applications may thus be treated differently between EU Member States. No medical indications are allowed on the product labels, as homeopathy is a highly individualised therapy.

Licensing requires a full set of data on the quality of the materials used in manufacturing. This includes data on the whereabouts of the herbal starting materials according to GACP (Good Agricultural and Collecting Practice) standards. These standards are frequently difficult to meet, as homeopathy usually requires only small quantities of plant material as starting substances, and the administrative burden in this context may easily exceed the economic benefit. This is especially difficult for plant materials included in Annex II of the CITES list.

Similarly, materials obtained from animals (e.g., ants, spiders, bees etc.) are now practically impossible to obtain. In the case of animal-derived materials it is not only the practical aspects and administrative burdens of sourcing, but also increased requirements with respect to quality and safety - e.g. safety with respect to transmissible diseases (viral infections, transmissible spongiform encephalitis etc.), which render the whole process of manufacturing uneconomic.

The registration of homeopathic preparations also calls for stability data for both the drug substance and the drug product. The corresponding guidelines of the European Medicines Agency are fully applicable. Practical application of the guidelines by the authority now leads to a questioning of the quality and stability of stocks of homeopathic starting materials and intermediate potentisations (technically dilutions).



The costs of stability testing aside, even in cases where the dilution level does not allow detection of the physical presence of the original starting material, the mandatory application of these rules adds to the cost of supplying starting materials so that production of these medicines is no longer an economic proposition. Ultimately manufacturers will either have to cease manufacturing many classical homeopathic preparations or increase the price to an unaffordable level. Both options will severely restrict the availability of homeopathic preparations.

2 ANTHROPOSOPHIC MEDICINAL PRODUCTS

Anthroposophic medicinal products include substances mostly from natural origin, i.e. derived from minerals, plants or animals, prepared in different levels of concentration for different routes of application, external, oral or parenteral. Some medicines are similar to herbal medicinal products, and some are prepared according to the guidelines laid down in homeopathic pharmacopoeias. Whichever route is followed, the anthroposophic specialities are produced using specific pharmaceutical procedures according to anthroposophic understanding.

The products are defined according to their (1) development, (2) manufacture and (3) use. They are

- developed in accordance to the anthroposophic knowledge of man and nature (anthroposophic knowledge includes common scientific knowledge)
- defined by their manufacturing procedure, that can be common to homeopathic medicinal products (e.g. European Pharmacopoeia or German Homeopathic Pharmacopoeia) or specifically anthroposophic (Pharmacopoeia Helvetica, Anthroposophic Pharmaceutical Codex)
- intended for use according to the principles of anthroposophic medicine.

The EU Community code relating to medicinal products for human use, Directive 2001/83/EC, does not recognise anthroposophic medicinal products as such. Some can be registered as homeopathic and others as herbal medicinal products. However the most typical and widely used anthroposophic medicinal products cannot be authorised either as homeopathic or as herbal medicines. As a consequence they should be authorised by the ‘normal rules’ governing pharmaceutical medicines. However, these rules are not appropriate for the special characteristics of the products and their use in the practice of anthroposophic medicine.

To date, the only European countries that have authorised a full range of anthroposophic medicinal products are Germany and Switzerland. In both countries the medicines legislators⁶⁹ as well as the competent authorities⁷⁰ have developed and implemented appropriate rules to allow a feasible market access to the wide range of anthroposophic medicinal products guaranteeing a high level of quality, safety and effectiveness.



69 - Germany: Law on the circulation of medicinal products (Gesetz über den Verkehr mit Arzneimitteln) Art. 4, (33); Switzerland: Law of the Swiss Institute of Medicinal Products concerning the simplified authorisation of complementary and phytomedicines (Verordnung des Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung von Komplementär und Phytoarzneimitteln) Art. 4, 2f.

70 - Germany: BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices) Switzerland: BAG - Bundesamt für Gesundheit (Federal Institute of Health)



Anthroposophic medicinal products have a long established use in several EU/European countries; on the basis of this long-term use, they have proven safe use. They are also produced to a high quality. They should be made available to all EU patients/users on the base of an appropriate rational regulatory scheme.

Recently work has been started to develop the scientific basis for a permanent regulatory framework for anthroposophic medicinal products in Europe. For this task, a 'European Scientific Cooperative on Anthroposophic Medicinal Products', ESCAMP, has been established as an independent non-profit organisation. ESCAMP works to develop standards for the scientific assessment of safety and efficacy/effectiveness of these products, following a system approach. This comprises [a] a description of the therapy system, [b] an empirical evaluation of the whole system and [c] an evaluation of its components, the anthroposophic medicinal products themselves. Based on this scientific work, and taking into account existing regulatory provisions in the EU, a rational regulatory scheme can be developed.

It is intended that the ESCAMP initiative will contribute substantially to the process of inclusion of anthroposophic medicinal products into the Community code relating to medicinal products for human use.

3 HERBAL MEDICINAL PRODUCTS

In 2001 the EU adopted the new Directive 2001/83/EC for all pharmaceutical products. This Directive required documented scientific evidence for the efficacy and safety of all pharmaceuticals, including herbal medicines. However, it soon became clear that applying such stringent demands for the quality, safety, and efficacy of herbal medicines with their characteristic complex chemical composition (in contrast to pharmaceutical drugs generally comprising a single chemical entity) would mean that the majority of herbal medicines could not fulfil these criteria and would consequently disappear from the European market.

TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMP)

To remedy the situation, in 2004 the EU Parliament and Council amended Directive 2001/83/EC by passing into law Directive 2004/24/EC. This allows the registration of traditional herbal medicines under a Traditional Use Registration (TUR) scheme, whereby documentation demonstrating clinical efficacy (usually verified in clinical trials) is replaced with a documentation proving long-term traditional use as stipulated in Article 16c of the Directive: '...[If] the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community [EU-member states]' then it can qualify as a 'traditional herbal medicinal product' (THMP).



The TUR provisions were intended to provide a framework under which herbal products demonstrating the required number of years of safe traditional use could enter the pharmaceutical regime of the EU. The requirement to demonstrate at least 15 years traditional medicinal use in EU Member States, all having established pharmacovigilance systems, meant that the safety of the herbal medicine in question as well as its therapeutic indications based on traditional use was acceptable throughout the EU. Directive 2004/24/EC also established the Committee on Herbal Medicinal Products (HMPC) at the European Medicines Agency (EMA), which to date has published more than 100 official monographs (community herbal monographs) for herbal substances and preparations, specifically including information on the traditional use. The HMPC has also released key guidelines on quality requirements for herbal remedies.

Directive 2004/24/EC restricts THMPs to formulations containing herbal materials and some specified mineral ingredients, and, of course, no potentially toxic ingredients are allowed. Under this scheme minerals included in such preparations can only have an ancillary mode of action. This excludes minerals or vitamins in higher dosage from registration (as these would no longer be considered ancillary), along with substances of animal or mineral origin such as pollen, propolis, or clarified butter (a typical constituent of Ayurvedic preparations) which have an established food use or for example medicinal clays. The scope of the Directive needs to be enlarged to include these simple non-plant substances as has also been discussed by the Commission in its communication to the Council and European Parliament.⁷¹

⁷¹ - Communication from the Commission to the Council and the European Parliament concerning the report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products. Brussels, 29.9.2008, COM(2008) 584 final.

Formulations are based on traditional empirical knowledge without the need for biomedical-scientific research to support the rationale of composition. This creates a new route to market for herbal formulas based on traditional empirical use.

Herbal medicines may also occasionally be licensed via a full market authorisation either like conventional pharmaceuticals or under well-established use, but the required level of research to validate these market authorisations (e.g. clinical trials) is lacking for most herbal medicines and so the TUR scheme is currently the most favourable route to market for traditional herbal medicinal products.

The following paragraphs highlight factors that currently undermine the success of the TUR scheme. The final part of this section suggests practical ways in which the European Commission and Parliament can improve the Traditional Herbal Products Directive to ensure an unrestricted but safe supply of herbal products onto the European market thereby making a valuable and affordable contribution to 21st century healthcare.

SLOW UPTAKE OF GRANTED TUR IN ONLY A FEW MEMBER STATES

The success of the TUR scheme can be measured by the numbers of granted registrations. Since the new legislation for TUR was enacted in 2004, just over 1000 THMPs have been registered throughout the EU.⁷² Although at first sight this may appear a satisfactory number of registrations, this figure is less than impressive when one takes into account that this is the total number of registrations achieved in a decade by all 28 Member States together. Moreover, the same single herbal product has often received registration in more than one Member State and is therefore counted several times.

The registration figures also demonstrate that the chances of successful registration depend on in which Member State the application is made. Four Member States (UK, Poland, Germany and Austria) have granted the majority of all registrations. In contrast, during the last 10 years the majority of Member States have registered only a few THMPs - often less than ten products. For example, France received 160 applications but has granted only 7 registrations.

Although Germany is one of the leading Member States in respect of total registrations, it nevertheless has granted only 154 registrations out of 426 applications. At the time of the EMA report in 2012, 149 applications were still under assessment whilst 123 applications had failed or been withdrawn.⁷³ Whilst the 1000 or so applications recorded by the Commission relate to a total of 134 different plants in mono-preparations; the majority of registrations represent only 21 commonly used medicinal plants.⁷⁴

72 - www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000208.jsp&mid=WC0b01ac05800240cf#. Accessed 23/8/14.

73 - Uptake of the traditional use registration scheme and implementation of the provisions of the Directive 2004/24/EC in EU Member States. EMA/322570/2011 Rev. 3 dated 8 May 2013.

74 - Ibid

Registration fees vary considerably between Member States. For example in Italy the registration of a traditional herbal medicinal product is currently invoiced at approximately €50.000 but the same registration is considerably less expensive in other Member States. Consequently, in Italy only 5 TUR applications have been successfully granted in a 10-year period.

Because the majority of Member States have only granted a handful of TUR, the current total number of THMPs is manifestly insufficient for the needs of EU citizens. Moreover, given that the number of newly registered THMPs is increasing only slowly and the process of registration can take years to complete, it is evident that the THMPD registration scheme is far from being harmonised and that the TUR is limiting rather than enabling the availability of herbal products. Because of TUR's shortcomings, herbal medicine in Europe is losing its unique range and diversity as well as being inhibited from developing its significant potential to help meet the health needs of EU citizens.

Other problems arise from the overly restrictive focus of some Member States on hypothetical risks. For example, this overcautious approach currently prevents any herb containing furocoumarins (e.g. those from the genus *Angelica*) from being registered, regardless of the fact that the genus *Angelica* constitutes one of the most important medicinal plant families with over 60 species of medicinal plants used on a worldwide basis.⁷⁵ Similar problems are caused by the requirement for genotoxicity data, which is not defined by EU Directive 2004/24/EC and which is interpreted differently by the various Member States despite the guidance of the HMPC which simplifies this process.^{76, 77, 78}

In addition, the stipulation requiring 15 years use within the EU restricts the registration of herbal medicines from non-European medical traditions. In reforming TUR, means must be found to recognise traditional medicines from outside the EU, in accordance with the spirit of the THMPD (2004/24/EC) that states:

'The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Pre-clinical tests do not seem necessary, where the medicinal product on the basis of the information on its traditional use proves not to be harmful in specified conditions of use. However, even a long tradition does not exclude the possibility that there may be concerns with regard to the product's safety, and therefore the competent authorities should be entitled to ask for all data necessary for assessing the safety.'



75 - Sarker SD, Nahar L (2004). Natural medicine: the genus *Angelica*. *Current medicinal chemistry*, 11:1479-1500.

76 - Guideline On The Assessment Of Genotoxicity Of Herbal Substances/Preparations, Doc. Ref. EMEA/HMPC/107079/2007

77 - Concept paper on selection of test materials for genotoxicity testing for traditional herbal medicinal products/ herbal medicinal products an annex to Guideline on the Assessment of Genotoxicity of Herbal substances/preparations (EMA/HMPC/107079/2007). London, 15 July 2008 Doc. Ref. EMEA/HMPC/315413/2008.

78 - Kelber O et al (2014). Assessment of genotoxicity of herbal medicinal products: application of the 'bracketing and matrixing' concept using the example of *Valerianae radix* (valerian root). *Phytomedicine*. 21(8-9):1124-1129.



SUMMARY

Member States evidently need encouragement from the Directorate General for Health and Consumer Affairs (DG SANCO) to harmonise the TUR scheme. The number of TUR granted by Member States and the number of herbal species included in the TUR should be closely monitored. Member States should be encouraged to increase the number of products granted TUR.

LIMITED SCOPE OF CURRENT TRADITIONAL USE REGISTRATION SCHEME

These limitations of the THMPD are made worse because the THMPD Directive 2004/24/EC currently makes no provision for Asian traditional systems of medicine, such as Ayurveda (from the Indian subcontinent) or traditional Chinese medicine (TCM). This serious omission has been openly acknowledged by the Commission in its 2008 communication to the Council and the European Parliament.

*'Medical traditions such as those mentioned above (i.e. anthroposophic, Ayurvedic, Chinese, Kampo, Korean, Mongolian, Thai, Tibetan, Unani, or Vietnamese medicine) are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed.'*⁷⁹



79 - Communication from the Commission to the Council and the European Parliament concerning the report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products. Brussels, 29.9.2008, COM(2008) 584 final.

Unfortunately, the Commission's call for a separate extended regulatory framework for these traditional medicine systems has not had any practical response to date and few herbal products from these traditions have gained TUR registration. For example, at the time of writing, only one traditional Chinese medicine herbal product has been registered as a THMP.⁸⁰ Consequently, the use of such herbal medicines remains a grey area in many Member States.

The current limited interpretation of possible therapeutic indications permitted by the HMPC also needs broadening. 2004/24/EC Art 16a.1(a) states that THMPs

“have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment.”

It is recommended that the scope of indications displayed on THMPs should be extended to enable the marketing of traditional formulations for use ‘after being diagnosed by a physician or health practitioner’. Such wording is already in use in some Member States. For CAM practitioners, THMPs have an unrealised potential to play an important role in providing an effective and safe range of treatment. The current rather low number of THMPs is insufficient for the effective treatment of different disease modalities: CAM doctors and practitioners need a significantly expanded range and scope of herbal medicinal products to practise effectively. However, under the current arrangements, the TUR scheme is designed to register herbal medicinal products for sale over-the-counter direct to public without any professional intervention. Consequently its scope is limited to products designed to treat mild and self-limiting conditions and this does not allow for herbal medicinal products that are suitable for practitioner use.

HERBAL MEDICINES VS. FOOD SUPPLEMENTS

DG SANCO coordinates both the regulation of food supplements and pharmaceutical products including herbal medicinal products. It oversees the regulation of the former with the European Food Safety Agency (EFSA) and the latter with the European Medicines Agency (EMA). Unfortunately the borderline between these two categories is not clearly defined which leaves consumers, health professionals and the herbal industry confused about the status of herbal products.

In some Member States these remedies are classed as foods whilst in others they are considered medicines. European law is increasingly confusing about this classification as evidenced by a recent EFSA ruling which declared that Transitech®, a food supplement containing 6 herbs including rhubarb root (*Rheum officinale*) which contains anthraquinones known to have a laxative effect, can be considered a food and marketed as such with health claims.⁸¹

80 - E. van Galen, Medicines Evaluation Board of the Netherlands: In search of the tradition of non-Western herbal medicinal products. TradeReg 2013: Regulation of herbal and traditional medicinal products - European and global strategies. International Symposium. BfArM, Bonn (Germany), 30. September to 2. October 2013.

81 - www.efsa.europa.eu/en/efsajournal/pub/3412.htm. Accessed 18/11/13.

Currently Belgium, France and Italy are creating the “BELFRIT” list of botanical food supplements with accepted health claims, as a response to the restrictive approach of the EFSA in the process of health claim assessments for botanicals.⁸² For example, France has recently decided to adopt of a 600-strong, positive list of botanical foods based on the BELFRIT list.⁸³ This will undoubtedly add to the confusion and lack of harmonisation with respect to herbal products throughout the EU.

For the most part, food supplements have neither the required potency nor the controlled quality (e.g. defined designated active constituents) to treat disease. They are normally marketed for the purposes of health maintenance.

The only way to discourage a black/grey market, which has already started to emerge for these kinds of products, is to adopt a clear strategy that implements a consistent regulatory registration scheme for herbal medicinal products across the EU. The potential of the TUR scheme can only be achieved if DG SANCO strengthens the standing of THMPs and clarifies the therapeutic scope and differences as well as the borderline between herbs marketed as food supplements and herbal medicines.

Any regulatory scheme for these traditional medicine systems should take into account the fact that traditional formulations often comprise up to a dozen or more plant medicines in combination. The difficulty in providing the required quality assurance data (e.g. assessing marker phytochemicals in the end products) should not be underestimated in assaying herbal products comprising multiple plant components and, as discussed below, the expense involved can effectively mean production costs make these registrations financially impracticable. Quality assurance schemes adopted wholesale from processing conventional marketing authorisations are mainly designed to deal with a single chemical entity. These requirements are ill suited to assess the orchestra of chemicals present in a combination of several plant medicines in a single product.

Current registrations fees vary considerably between Member States. In Germany the registration of a traditional herbal medicinal product is currently invoiced at approximately €15,700 but the same registration is considerably less expensive in other Member States. The registration fee is only part of the total cost of achieving a traditional registration under the THMPD. The main costs occur with the development of validated analytical procedures and stability testing. Typically, the development of suitable methods of validation for quantitative assay costs around €10,000 to €15,000 in a GMP/GLP certified lab. Stability testing costs a further €40,000 to €60,000 for a single-herb preparation and, as mentioned, more for combination products. Registration costs for single-herbal products can easily run to €150,000 and beyond whilst the registration of new multi-herbal products under the THMPD costs at least €100,000 per product, depending on the amount

82 - www.direnzobiz.it/en/blog/item/179-belfrit-botanicals-in-food-supplements. Accessed 20/8/14.

83 - France adopts 60% of BELFRIT list for safe botanicals, <http://euronewscloud.com/2014/07/07/france-adopts-60-of-belfrit-list-for-safe-botanicals/> Accessed 20/8/14.

of expert work to be performed. The cost of registration also depends on the availability of Community Herbal Monographs on traditional use and/or on the existence of relevant monographs in the European Pharmacopeia. There are still only relatively few published Community Monographs for herbs from non-European traditions. Where no monographs exist, the required data must be developed, which significantly adds to the costs of registration. Many herbal medicine suppliers/manufacturers are small and medium enterprises (SMEs) producing numerous herbal products in small volumes and many of these consist of multi-herbal mixtures. These SMEs simply do not have the financial resources to fund multiple THMP licence applications and are consequently being driven out of business.

FUTURE STRATEGIC OPTIONS FOR DG SANCO

- DG SANCO should guide Member States to adopt a consistent application of the TUR scheme. Within the EMA, the coordinating committee, the Herbal Medicinal Products Committee, also needs guidance from DG SANCO as the HMPC has to work on the basis of majority voting. This voting process currently permits Member States with a poor record of THMP-registrations to slow down further the TUR implementation of the THMPD across the EU. For this reason, the HMPC needs support from DG SANCO to:
 - 1 strengthen its status and coordinating power with respect to the Member States
 - 2 extend and interpret the scope of traditional herbal registrations to enable a much more flexible TUR registration scheme.
 - 3 speed up the registration process
 - 4 provide a harmonised approach in Europe for all CAM medicinal and food status products.
- Although the THMPD 2004/14/EC provides that Member States should take ‘due account’ of positive TUR decisions taken by other Member States regarding a THMP registration, this remains the exception. Positive decisions on registering a herbal product taken by one Member State are more often than not ignored by other Member States for no apparent reason. In order to achieve a harmonised market, the recognition by all Member States of positive TUR decisions taken with regard to a THMP by a single Member State should be the rule rather than the exception. The process of mutual recognition procedure (MRP) has just started for THMPs. MRP progress has to be monitored and further encouraged by DG SANCO.
- The potential of the TUR scheme can only be achieved if DG SANCO clarifies the therapeutic scope and differences as well as the borderline between herbs marketed as food supplements and herbal medicines.



LEGISLATIVE OPTIONS FOR THE EUROPEAN PARLIAMENT

To facilitate the use of herbal medicinal products the European Parliament should extend the scope of the existing Directive 2004/24/EC to:

- Include other medical traditions, which have proof of a longstanding medical tradition, but cannot qualify under the 15/30-year regime of traditional use.
- Broaden the scope of indications applicable to THMPs to include more indications suitable for THMPs.
- Extend the registration scheme for products intended exclusively for the use of statutorily regulated healthcare professionals.
- Ingredients of THMPs can be herbal substances, herbal preparations and minerals. The scope of this regulation is interpreted and applied differently by Member States. In order to compete with food supplements, common foods such as honey, butter fat (ghee) or minerals, which are used in traditional systems of medicine should be allowed in THMPs.

GENERAL CONCLUSIONS

The 'Action plan for herbal medicines 2010-2011' and 'Work Programme for 2012-2015' of the Committee on Herbal Medicinal Products (HMPC) at the European Medicines Agency mark some progress in improving the scope and application of the THMPD. However it is evident that the THMPD (Directive 2004/24/EC) requires thorough reassessment to ensure that there is a workable regulatory framework for traditional herbal medicinal systems in the EU.

Such a revision along the lines suggested above will act to discourage a black/grey market assuring the supply of high-quality medicinal herbal products and supporting the development of traditional medicine systems and herbal medicine/phytotherapy in the interests of EU citizens.

VI

Investing in CAM research

I CURRENT UNSATISFACTORY SITUATION

There is a huge disparity between public funding for conventional drug research and that available for CAM research. Whilst CAM may improve health, reduce disease, and reduce health costs, the CAM sector alone cannot be expected to support the research to prove these possibilities. Like mainstream medical research, there is a social responsibility for government to fund such research. As for conventional medicine there should be industry-independent funded research.

The CAMbrella report confirms that European research in the field of CAM is limited and that there is almost no significant investment in any EU Member State in a CAM research structure or strategy. The derisory public investment in this field in Europe stands in stark contrast to the relatively large investments in Australia, Asia and North America. The CAM industry is small and there are no major financial or/and industrial interests driving research efforts in this field. Scientific bias hampers the free exchange of ideas, concepts, treatment techniques and comparison of clinical outcomes. CAM is organised mostly in private provider settings, thus the academic experience among CAM providers is limited, although increasing, and there are few academic research centres, resulting in a substantial lack of funding for research programmes. Career opportunities in an academic setting are rare.

To improve this untenable situation, it is essential to include further CAM research in national health research strategies and especially in the EU research programme Horizon 2020. Part III of this programme 'Priority Social Challenges' and the specific objective 'health, demographic change and well-being' offers the ideal organizational prerequisite for a further engagement of the EU in CAM research projects.⁸⁴

84 - Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020), COM (2011) 809 final, Part III

85 - Fischer F et al (2014). A research roadmap for complementary and alternative medicine - what we need to know by 2020. *Forschende Komplementärmedizin*, 21(2):e1-e16. A short version was published as Fischer FH et al (2014). High prevalence but limited evidence in complementary and alternative medicine: guidelines for future research. *BMC Complementary & Alternative Medicine*, Feb 6;14:46. Table and the following text include several excerpts from this paper.

2 ROADMAP FOR RESEARCH INTO CAM

One of the most pressing findings of the CAMbrella Project is the lack of sufficient, reliable and comparable data about CAM in Europe. This applies to more or less all aspects of CAM, e.g. understanding and modalities of CAM, the use of and availability of CAM for patients and citizens, the innovative role of CAM in public healthcare, efficacy, safety and cost-efficiency of CAM etc.

The CAMbrella roadmap⁸⁵ provides an outline for quantitative and qualitative research, suggesting six core areas covering important gaps in knowledge (see table below).

KEY RESEARCH AREAS	AIM	RECOMMENDATION	RESEARCH METHODS	SPECIFICS
CAM PREVALENCE	To obtain valid, comparable and comprehensive data on prevalence of CAM use	Structured EU-wide approach	Cross-sectional studies	Using standard definitions, develop standardized questionnaires for surveys in European languages
NEEDS AND ATTITUDES OF CITIZENS AND PROVIDERS	To address issues that are relevant to the EU public	Obtain data on how the diversity of the EU influences attitudes about CAM	Cross-sectional studies; qualitative interview studies	Involve the public as stakeholders in project development
CAM SAFETY	To allow the risks of CAM to be estimated	Address safety in studies and establish an EU-wide monitoring system	Observational studies; clinical studies; single case studies	Clarify safety terminology; address safety in CAM studies where appropriate
COMPARATIVE EFFECTIVENESS RESEARCH	To support clinical and health care policy decision making with suitable research data	Future research should primarily investigate CAM in real-world settings	Comparative effectiveness research, including pragmatic clinical trials	Compare meaningful alternatives; include health economic evaluations
EFFECTS OF CONTEXT AND MEANING	Understand the extent to which the clinical effects of CAM are due to non-specific treatment effects	Assess the nature, size and influence of potential non-specific treatment effects	Mixed methods (qualitative studies within clinical trials)	Research question is not specific to CAM, but of general interest
MODELS OF CAM INTEGRATION	To investigate different models of CAM integration	Describe, evaluate and further develop models for CAM integration	Mixed methods	Include the public's view on models of CAM integration



1 RESEARCH INTO THE PREVALENCE OF CAM USE

A clear picture of CAM use is crucial for providers, purchasers and health policy makers alike. CAMbrella recommends that the prevalence of CAM use in the EU be assessed using large, cross-sectional studies. A consistent approach that allows meaningful comparisons of CAM prevalence across EU member states needs to be based on a clearly defined set of common CAM practices and treatments. A common survey methodology, including standardized questionnaires translated into the various national languages, is essential to ensure the comparability of data. This approach must also be based on the principles of good epidemiological research.

2 CITIZENS' ATTITUDES AND NEEDS REGARDING CAM

A structured approach to CAM research that is relevant to the public's needs requires comparable data from all EU member states so that studies can be conducted in parallel in several countries whenever possible. Examples of such approaches include:

- large scale surveys based on validated questionnaires;
- qualitative interviews and fieldwork studies with in-depth explorations of local experiences and practice;
- interdisciplinary research involving mixed-methods with CAM providers and clients as research partners.

3 SAFETY

CAMbrella suggests addressing CAM safety on a regular basis. Data from clinical trials should be routinely used to investigate the frequency of the more common side effects, since comparisons to adequate control groups help establish risk-benefit ratios. The reporting of serious side effects in single case studies should be fostered. In the long run, developing a European monitoring system for CAM safety may be desirable but would require more thorough information about CAM prevalence and provision.

4 COMPARATIVE EFFECTIVENESS RESEARCH

Patients and providers need to know when CAM is a reasonable choice, as this enables them to make informed decisions in real-world situations. Unfortunately, clinical research to date has often focused on the specific effects of CAM in ideal and standardized clinical situations that are rarely experienced in clinical practice. For this reason there is a need to investigate neglected real-world scenarios in clinical research.

Current trends in conventional medicine also address the limited impact of efficacy studies on decision-making in clinical practice. In response, standards for patient-centred outcomes research are currently being developed internationally.

The movement in conventional medicine towards more comparative effectiveness research has focused strongly on evaluating different treatment options by including a more heterogeneous patient sample, using real-world treatment protocols that are less standardized focusing on patient-centred outcomes.

The advantage of comparative effectiveness research is its capacity to evaluate CAM as an optional add-on to conventional treatment, or as an alternative to it. Such research also allows for the evaluation of complex interventions, medium and long-term clinical effects, and cost-effectiveness in comparison to treatment alternatives. Furthermore, comparative effectiveness research calls for stakeholder involvement to help ensure external validity and relevance.

Research in real-world settings is the most promising approach to identifying the possible contributions of a variety of CAM modalities to the health of the EU public. Future research on CAM should emphasize comparative effectiveness analysis as a way to obtain data that are valuable to all stakeholders and provide useful guidance in a pragmatic clinical context.

5 CONTEXT AND MEANING EFFECTS

Valid and reliable tools are needed to assess components of meaning and context effects, as doing so will facilitate clinical research and allow study results to be compared. Special emphasis should be placed on the question of whether CAM is associated with effects that are different from those in conventional medicine. Understanding the mechanisms behind these effects will help in identifying the appropriate scope and limits of CAM, as well as those of conventional medical treatments. Such research could lead to a better understanding of the mechanisms underlying CAM, clarify the value of CAM for patients and the general public, and help politicians when making reimbursement decisions. Patient and provider expectations, and the time required for diagnosis and treatment, are examples of context and meaning effects that should be included in clinical research on CAM. Researchers should attempt to differentiate these from the intrinsic impact of any specific intervention. However, given the importance of context and meaning effects in all fields of medicine, we believe that research into this area should be a priority.

6 HEALTHCARE INTEGRATION

The various models of CAM provision in the EU are likely to affect healthcare in different ways. Provision outside of publicly funded healthcare allows a free choice of treatments and respects the freedom of individuals within the EU as providers or users of CAM. However, safety and equity of access might be easier to achieve in countries where CAM is provided within the public healthcare system.





At the moment, there is no consensus about the best model for integrating effective CAM treatment, such as acupuncture for pain, into the healthcare system. Also, it is unlikely that there is one model that can fit all the needs of the different regulatory systems. CAMbrella recommends evaluating concurrently the various existing models of CAM integration to identify their strengths and limitations. Furthermore, innovative models of CAM provision should be developed to address the needs of the public on a pragmatic basis.

3 ACHIEVING CAMBRELLA'S VISION

In order to achieve CAMbrella's vision, there is need for stronger institutional support of CAM research. So far, Europe has lagged behind North America, Asia and Australia in terms of structural research funding in CAM. Increased institutional support at the European level is needed to promote research on the topics proposed in the roadmap and to ensure methodological quality.

CAMBrella recommends first establishing a European CAM research coordination office to foster systematic communication between EU governments, the public, charitable and industry funders, researchers, and other stakeholders. Its aim would be to inform the public about recent developments in CAM research, and to disseminate information about research strategy developments and funding among researchers.

CAMBrella proposes an EU-funded European Centre for CAM (ECCAM) comparable to the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health in the US. This depends on political will at the EU and Member State level. The aim of the centre would be to stimulate and support high-quality research on CAM in the EU through an independent research strategy aligned with EU health policy and through its own capacity to fund projects and fellowships. CAMbrella also recommends improving the quality of CAM research by investing in education, training and collaboration in the CAM research community across Europe and beyond.

VII

EUROCAM'S call for action





EUROCAM CALLS ON THE EUROPEAN COMMISSION

- to promote equitable access by citizens to CAM in Member States
- to promote harmonisation of information on CAM methods and CAM providers within the EU Member States in order to facilitate cross border movement for citizens and providers using CAM modalities
- to include CAM in all possible Community Actions dealing with health education and promotion, prevention and treatment of chronic disease, health inequalities and active and healthy ageing
- to encourage Member States to explore the ways in which CAM can contribute to sustainable healthcare systems in Europe including its role in health maintenance, health education, self-responsibility for health, motivation for healthy lifestyle change and less invasive and more cost-effective treatment of illness
- to propose the requisite draft directives, or amendments to existing directives, to ensure freedom of establishment and freedom to provide services for providers of CAM
- to initiate a process for the appropriate regulation of providers of CAM across the Union taking into account the full extent of the scope of action of CAM modalities across the healthcare spectrum from health maintenance and education to complementary treatment of illness
- to initiate, in cooperation with the stakeholders concerned, an appropriate revision of the regulations on the licensing and use of CAM medicinal products in Europe and in particular to act upon the suggestions outlined in the Commission Communication 2008, notably that ‘the suitability of a separate legal framework for products of certain traditions should be assessed’.⁸⁶
- to take up, following consultation with the CAM stakeholders, the recommendations of the CAMbrella 7th Framework Research Project on the funding of future research into CAM in Europe
- to ensure that the management of the programmes of the Commission – such as the Health for Growth, Horizon 2020, European Innovation Partnership on Healthy and Active Aging and other relevant programmes – gives an equitable opportunity to CAM projects to participate.

⁸⁶ - Commission Communication 2008 on the experience acquired as a result of the application of the provisions of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products

EUROCAM ALSO CALLS ON MEMBER STATES, AS REQUESTED BY WHO⁸⁷

- to formulate national policies, regulations and standards, as part of comprehensive national health systems to ensure appropriate, safe and effective use of CAM, and equitable access to it by citizens.
- to incorporate CAM into their national health systems.
- to establish systems for the qualification, accreditation or licensing of CAM providers.



EUROCAM CALLS ON THE EUROPEAN PARLIAMENT:

- to initiate and support an own-initiative report on CAM building on the conclusion of the ENVI committee's Workshop on Alternative Medicines in the European Parliament, taking account of the conclusions of the meetings of the EP MEP Interest Group on CAM and the findings of the CAMbrella 7th Framework Research Project.

87 - Approved at the 62nd session of 22 May 2009 and 67th session of 24 May 2014 of the WHO World Health Assembly – resolutions WHA 62.13 and WHA 67.18 respectively. See http://www.who.int/medicines/areas/traditional/trm_assembly_doc/en



- to call on the Commission to formulate a proposal for an independent and adequate regulation of medicinal products used in ‘traditional’ medicine in line with the Commission Communication 2008.⁸⁸
- to call on the Commission to propose the requisite draft directives to ensure freedom of establishment and freedom to provide services for providers of CAM
- to call on the Commission to ensure that the management of the programmes of the Commission such as Health for Growth, Horizon 2020, European Innovation Partnership on Healthy and Active Ageing and other relevant programmes gives an equitable opportunity to CAM projects to participate.

EUROCAM INVITES THE MEMBERS OF THE EUROPEAN PARLIAMENT

- to participate in the initiatives of their fellow MEPs in the Parliament Interest Group on CAM.

⁸⁸ - Commission Communication 2008. Op.Cit.

VIII

References





I SHORT DESCRIPTIONS OF INDIVIDUAL CAM MODALITIES

1.1 ACUPUNCTURE

Acupuncture is perhaps the best-known aspect of traditional Chinese Medicine (TCM) in the west. It aims to influence body functions and stimulate and restore the body's own regulatory system by using specific (acupuncture) points on the surface of the body. Besides the use of needles, the application of pressure (acupressure) and heat (moxibustion) are also traditionally used. Diagnosis and treatment are conducted in accordance with the presenting individual pattern of disharmony and are based on traditional concepts, centuries of clinical experience and on modern scientific basic research. Acupuncture can treat a wide range of complaints both organic and functional in origin. It is also well known for its application in pain management and modern research has confirmed its effectiveness in the treatment of low back pain, depression, the treatment of migraine and many other common conditions.^{89,90,91} Acupuncture can be combined with other therapeutic TCM techniques such as moxibustion, cupping, gua sha (a kind of rubbing therapy), herbs, dietetics, tuina (massage and manual therapy) and qigong (exercises, breathing, concentration). Acupuncture is often integrated in various therapeutic aspects of mainstream medicine.

1.2 AYURVEDA

Ayurveda (the 'science of life') is a system of traditional medicine native to the Indian subcontinent using methods for achieving physical, mental and spiritual health and well-being. Ayurveda emphasises prevention and a holistic approach to therapy and is practised as a form of CAM within the western world, where several of its methods, such as the use of herbs, massage, and yoga are applied on their own as a form of CAM treatment.

1.3 ANTHROPOSOPHIC MEDICINE

Anthroposophic medicine is a holistic and salutogenetic approach to medicine focusing on strengthening the patient's organism and individuality. The self-determination, autonomy and dignity of patients are central themes. Therapies are intended to enhance a patient's capacities to heal and include anthroposophic medicines as well as various art therapies like painting and sculpture therapy, music, singing and speech therapy, physiotherapy and massage, psychotherapy, curative education and social therapy - and eurythmy therapy in which special body movements are employed for therapeutic purposes.

89 - <http://www.nice.org.uk/guidance/CG88>.

90 - Hopton A et al (2014). Acupuncture, counselling or usual care for depression and comorbid pain: secondary analysis of a randomised controlled trial. *BMJ Open*, 4(5):e004964

91 - www.webmd.com/migraines-headaches/news/20120112/acupuncture-may-be-effective-for-migraines.

1.4 CHIROPRACTIC

Chiropractic is a healthcare profession that focuses on disorders of the musculoskeletal system and the nervous system, and the effects of these disorders on general health. Chiropractic care is used most often to treat neuromusculoskeletal complaints, including but not limited to back pain, neck pain, pain in the joints of the arms or legs, and headaches.

Chiropractic physicians or chiropractors practise a hands-on approach to healthcare that includes patient examination, diagnosis and treatment. They have broad diagnostic skills and are also trained to recommend therapeutic and rehabilitative exercises, as well as to provide nutritional, dietary and lifestyle counselling.

1.5 HERBAL MEDICINE

Herbal medicine – also called phytomedicine or phytotherapy – refers to using a plant’s seeds, berries, roots, leaves, bark, or flowers for medicinal purposes. Whole herbs contain many chemical constituents working synergistically together to treat disease and support the body’s own healing mechanisms (e.g. its immunity). Herbal medicine practice is rooted in hundreds of years of experience of using plant medicines which today is underpinned by the scientific study (pharmacognosy) of plant medicines and their chemical constituents. Herbal medicine is becoming mainstream as improvements in analysis and quality control along with advances in clinical research show the value of plant medicines in the treatment and prevention of disease. Apart from the herbal medicine itself, herbal practitioners will routinely offer advice on appropriate changes of lifestyle, diet and the adoption of stress-reduction techniques and exercise.



1.6 HOMEOPATHIC MEDICINE

Homeopathy is a whole medical system that originated in Germany. The fundamental idea of homeopathy is the Similarity Principle, which implies that substances capable of causing disorder in healthy subjects are used as medicines to treat similar patterns of disorder experienced by ill people. Homeopathic medicines are aimed to direct and stimulate the body’s self-regulatory mechanisms. Homeopathy is highly individualized while taking into account the symptoms and signs of the disease, the patient’s physical build, personality, temperament and genetic predispositions. Apart from homeopathic medication, advice on change of lifestyle, diet and substance-abuse behaviours, acquisition of stress-reduction techniques and exercise are part of the package of care.



1.7 KINESIOLOGY

Kinesiology is a uniquely client-specific approach to health and wellbeing. It uses 'Muscle Response Testing' to get feedback from the body at a sub-conscious, reflexive level. In response to gentle pressure, a locked muscle is seen as a positive response to an 'input stress' such as a statement, a memory, a food or an educational activity. A weak or unlocked muscle indicates a negative response, a lack of ease. Applied Kinesiology was first developed as a therapy in the 1960's by Dr. George Goodheart supported in his research by around 18 other chiropractors. One of these, Dr. John Thie offered the Touch for Health Kinesiology Synthesis, a sub-set of Applied Kinesiology to the general public. From there, kinesiology developed as a broad based stand-alone therapy.

During a kinesiology session the mental, chemical, physical, energetic and environmental aspects of a problem are dealt with simultaneously. Kinesiology offers a selection of techniques and remedies drawn from chiropractic, traditional Chinese medicine and other sources to support healing.

1.8 NATUROPATHIC OR TRADITIONAL EUROPEAN MEDICINE (TEM&N)

Rooted in Hippocratic, Mediterranean and middle-European traditional healing systems, TEM&N currently represents a pragmatic blend of traditional, scientific and empirical methods in the prevention and treatment of illness and the maintenance of health.

The principles and methods of TEM&N are taught so they can be adopted and practised by those seeking better health or health maintenance. The principles involved include:

- Understanding the human being as an integral part of nature achieving optimum health by having body, mind and spirit in harmony with the environment.
- Understanding and employing the inherent homeostatic and regulatory principles of the body's biological and biochemical and electromagnetic functions.
- Understanding the central importance of the interplay of the elements, temperament and constitution so that treatment is suited to individual need.
- Making an individual diagnosis based on the unique analysis of each case.
- Highlighting the necessary measures to achieve full health and prevention of disease. This includes appropriate individualised dietary and lifestyle advice suited to the specific individual.

TEM&N is a distinct healthcare profession, emphasizing the importance of prevention as well as offering treatment through the use of a variety of therapeutic methods and natural substances that encourage individuals' inherent self-healing eliminative and constructive processes to obtain optimum health. TEM&N professionals comprehend human beings and other living creatures as a vital individual unity of body, soul and spirit.

Current methods of practice include: cupping, massage, treatment with leeches, bloodletting, spagyric therapy, apitherapy, balneotherapy, hydrotherapy, relaxation exercises, movement therapy, reflexology, neural therapy, nutritional advice, vitamin and mineral therapy, fasting, herbalism/ phytotherapy, the use of essential oils, psychological counselling, stress management, lifestyle regulation and others.

1.9 OSTEOPATHY

Osteopathy is a system of medicine that emphasizes the theory that the body can heal itself given normal, healthy structural relationships, environmental conditions, and nutrition. Treatment attends to body mechanics and manipulative methods in diagnosis and therapy. It is a contact and patient-centred healthcare discipline, that emphasises the interrelationship of structure and function of the body, facilitates the body's innate ability to heal itself and supports a whole-person approach to all aspects of health and healthy development, principally through manual treatment.

The practice of osteopathy uses current medical and scientific knowledge to apply the principles of osteopathy to patient care. Scientific plausibility and evidence-based outcomes have a high priority in patient treatment and case management. Osteopathy provides a broad range of approaches to the maintenance of health and the management of disease. It embraces the concept of the unity of the individual's structure (anatomy) and function (physiology); as such osteopathy is a patient-centred rather than disease-centred system of healthcare.

An essential component of osteopathy is its great attention to body mechanics and its manual methods in diagnosis and therapy. Osteopathy was developed as a means to facilitate normal self-regulating/self-healing mechanisms in the body by addressing areas of tissue strain, stress or dysfunction which may impede normal neural, vascular and biochemical mechanisms.



1.10 REFLEXOLOGY

Reflexology is the study and practice of treating points and areas in the feet and hands that relate to corresponding parts of the body. Using precise hand and finger techniques, a reflexologist may improve circulation, induce relaxation and enable homeostasis. This encourages the person's own healing systems to be activated to maintain wellbeing.

Reflexology has been practiced for over 4000 years, its practice dates back to Ancient Egypt, India and China. It was introduced to the West by a surgeon, Dr William Fitzgerald, who published an article in 1917 on Zone Therapy or Relieving Pain at Home. In the 1930's a physiotherapist, Eunice Ingham, further developed his theory which become known as reflexology.

Reflexology is a holistic treatment tailored to the individual that can be received by anyone at any age, from newborn babies to the elderly, although there may be times when it is not a suitable treatment. Reflexology is often used alongside allopathic healthcare to increase health and wellbeing. Professional reflexologists do not claim to cure, diagnose or prescribe.



1.11 SHIATSU

Shiatsu is an autonomous natural healthcare system which originated in Japan, and is influenced by traditional Chinese medicine and more recently Western knowledge. It derives its theoretical and practical roots from the ancient traditions of East Asian philosophies and healing and the holistic understanding of life and health based upon them. Its aim is to stimulate and support the processes of natural self-healing, well-being and personal growth, and to maintain health, through balancing the energetic system of a person. The method uses the application of pressure or energetic touch on specific points, channels (meridians) or areas of the body to balance the circulation of the body's energy (Ki in Japanese or Qi in Chinese).

Treatment involves brief or sustained pressure with thumbs, hands, elbows, knees and feet to meridians and tsubo (pressure points) and to other physical structures. Treatment may also include rotations and stretching of limbs, joints and meridians. Shiatsu is usually given on a soft mat on the floor.

Shiatsu enhances self-awareness and sensitivity, and releases tension. It also supports and nourishes a person's life-force. Applied by a practitioner with appropriate training, shiatsu promotes general well being and can be used as a preventative healthcare method. It can also assist people through crisis, difficult life phases and processes of change. It can treat people presenting with a wide variety of physical conditions.

1.12 TRADITIONAL CHINESE MEDICINE (TCM)

Traditional Chinese medicine (TCM) originated in ancient China and has evolved over thousands of years. It encompasses many different practices, including acupuncture, moxibustion (burning an herb above the skin to apply heat to acupuncture points), Chinese herbal medicine, tuina (Chinese therapeutic massage), gua sha (a rubbing therapy), dietary therapy, and tai chi and qigong (practices that combine specific movements or postures, coordinated breathing, and mental focus). Traditional Chinese medicine dates back more than 2,500 years. Traditional systems of medicine also exist in other East and South Asian countries, including Japan (where the traditional herbal medicine is called Kampo) and Korea. Some of these systems have been influenced by TCM and are similar to it, but each has developed distinctive features of its own.

1.13 TIBETAN MEDICINE

Tibetan medicine, Sowa Rigpa (the ‘science of healing’), is a system of traditional medicine native to Tibet (and adapted in parts of India, Nepal, Bhutan, Mongolia, Himalayan regions, Siberia, etc.). It is a complete traditional medical system with all divisions of physiology, pathogenesis, general and special pathology, diagnosis and treatment. Based on a threefold humoral theory, body-mind concept and Buddhist psychology, Tibetan Medicine is a holistic medicine, which aims to balance the three aspects of life: body, energy and mind by internal and external therapies as well as by the introduction of health promoting self-administered exercises. It employs a complex approach to diagnosis and utilizes lifestyle and dietary modification, medicines composed of natural materials (e.g. herbs and minerals) and physical therapies (e.g. Tibetan moxibustion & Tibetan massage therapy etc.) to treat illness.

1.14 YOGA

Yoga is a systematic practice of physical exercise, breath control, relaxation, diet control, positive thinking and meditation aimed at developing harmony in the body, mind, and environment. The practice entails low-impact physical activity, postures (called asanas), breathing techniques (pranayama), relaxation, and meditation.

Yoga is an ancient system of physical and mental practices that originated during the Indus Valley civilization in South Asia. The fundamental purpose of yoga is to foster harmony in the body, mind, and environment. The origin of the word ‘Yoga’ is a Sanskrit word Yog meaning ‘union’. Yoga is a union of the organ systems in the body with the consciousness in the mind.

Yoga is a low-cost self-help approach to well-being. Regular practice of yoga can lead to reduced stress levels, improved flexibility and muscle strength, improved posture, improved awareness of the physical body and the self. As it is not necessary to be in peak physical condition to practice yoga, it is an ideal activity for sedentary people and for seniors as well as for those who are more active.



2 EUROPEAN CAM UMBRELLA ORGANISATIONS, COLLABORATING IN EUROCAM

- **ANME** - Association for Natural Medicine in Europe
- WWW.ANME-NGO.EU
ngo representing the interests of traditional naturopathy and of natural medicine
- **ECCH** - European Central Council of Homeopaths
- WWW.HOMEOPATHY-ECCH.ORG
European association uniting national associations of homeopathic practitioners
- **ECH** - European Committee for Homeopathy
- WWW.HOMEOPATHYEUROPE.ORG
European association uniting national associations of homeopathic doctors
- **ECPM** - European Council of Doctors for Plurality in Medicine
- WWW.ECPM-EUROPE.CH
European association uniting national associations of naturopathic doctors
- **EFHPA** - European Federation of Homeopathic Patients' Organisations
- WWW.EFHPA.EU
European association uniting national associations of patients' organisations for homeopathic medicine
- **EFPAM** - European Federation of Patients' Associations for Anthroposophic Medicine
- WWW.EFPAM.EU
European federation uniting national patients' associations for anthroposophic medicine
- **EHTPA** - European Herbal & Traditional Medicine Practitioners Association
- WWW.EHTPA.EU
European association uniting national associations of herbal & traditional medicine practitioners
- **ETCMA** - European Traditional Chinese Medical Association
- WWW.ETCMA.ORG
European association uniting national associations of TCM practitioners
- **EUAA** - European Ayurveda Association -
WWW.EUROAYURVEDA.COM
European umbrella organisation of European Ayurvedic organisations

- **EURAMA** - European Ayurveda Medical Association
WWW.AYURVEDA-ASSOCIATION.EU
European association uniting Ayurvedic doctors
- **ICMART** - International Council of Medical Acupuncture and Related Techniques -
WWW.ICMART.ORG
Global organisation uniting national medical acupuncture associations
- **IVAA** - International Federation of Anthroposophic Medical Associations
WWW.IVAA.INFO
Global organisation uniting national associations of anthroposophic doctors

3 RELEVANT EU HEALTH POLICY ORGANISATIONS

HMA - Heads of Agencies

The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The Heads of Medicines Agencies co-operates with the European Medicines Agency and the European Commission in the operation of the European Medicines Regulatory Network. The national competent authorities represented in the HMA are responsible for the registration and market authorisation of medicinal products, including homeopathic, herbal and anthroposophic medicinal products, in the European Union and Norway, Iceland, and Liechtenstein.

See: WWW.HMA.EU/INDEX.HTML.

HMPWG - Homeopathic Medicinal Products Working Group

An expert group of the Heads of Agencies, dealing with regulatory issues of homeopathic and anthroposophic medicinal products. On their website several useful guidance documents can be found. See: WWW.HMA.EU/79.HTML

HMPC - Committee on Herbal Medicinal Products

The HMPC at the European Medicines Agency provides EU Member States and European institutions its scientific opinion on questions relating to herbal medicinal products. The HMPC's activities aim at assisting the harmonisation of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework. See:

WWW.EMA.EUROPA.EU/EMA/INDEX.JSP?CURL=PAGES/ABOUT_US/GENERAL/GENERAL_CONTENT_000264.JSP

EDQM - European Directorate for the Quality of Medicines and HealthCare

Part of the administrative structure of the Council of Europe, this department provides recognised common standards for use by healthcare professionals and others concerned with the quality of medicines including herbal and homeopathic medicines. The European Pharmacopoeia monographs and other texts are designated to be appropriate to the needs of regulatory authorities, those engaged in the control of quality, and manufacturers of starting material and medicinal products; it contains several monographs on herbal and homeopathic medicines. See:

WWW.EDQM.EU/EN/EDQM-HOMEPAGE-628.HTML

4 RELEVANT GLOBAL ORGANISATIONS**WHO - World Health Organization**

The WHO's Traditional Medicine Strategy 2014-2023 aims to build the knowledge base for national policies and strengthen quality assurance, safety, proper use and effectiveness of traditional and complementary medicine through regulation. It also aims to promote universal health coverage by integrating traditional and complementary medicine services into health care service delivery and home care. The WHO uses the term 'traditional medicine' when referring to Africa, Latin America, South-East Asia and/or the Western Pacific, whereas 'CAM' is used when referring to Europe and/or North America (and Australia). When referring in a general sense to all of these regions, the WHO uses the comprehensive term TM/CAM. See:

WWW.WHO.INT/MEDICINES/PUBLICATIONS/TRADITIONAL/TRM_STRATEGY14_23/EN/

EUROCAM
C/O IVAA OFFICE
194 RUE DU TRÔNE
1050 BRUSSELS
BELGIUM
EMAIL: INFO@CAM-EUROPE.EU
WEBSITE: WWW.CAM-EUROPE.EU



EUROCAM
C/O IVAA OFFICE
194 RUE DU TRÔNE
1050 BRUSSELS
BELGIUM
EMAIL: INFO@CAM-EUROPE.EU
WEBSITE: WWW.CAM-EUROPE.EU