

# European Policy Brief

The Roadmap to  
Future CAM Research  
in Europe



## What is CAM?

'Complementary and Alternative Medicine' (CAM) is the most commonly accepted term for the range of practices offering a 'whole person' approach to health. CAM is practised mostly in private practice by medical doctors and practitioners trained in the specific treatments. It is provided mainly outside conventional health care, although certain practices are used in conventional medical settings in a small number of EU countries. The most prominent CAM modalities in the EU are acupuncture and homeopathy, followed by herbal medicine (phytotherapy) and reflexology.



## The role of CAM in European health care

CAM is used by about 100 million EU citizens (that is 20% of the population). CAM is seen by European citizens and patients as the health approach that allows them to experience the attention to and individualized treatment of their specific health needs that they very often miss in conventional medicine.



## The problems

- There is no clear terminology – definitions vary and differ from one language and culture to another.
- Regulations and laws on CAM provision differ greatly – every member and associate state, sometimes even regions within one member state, has different rules regarding use and provision.
- All stakeholders, including citizens, patients, health care providers and policy makers, lack access to reliable information about CAM.
- There is also a lack of reliable research data: neither epidemiological facts such as the prevalence of CAM, nor clinical facts such as outcome oriented research, are available, due to the lack of research.
- CAM is still not taken seriously by a number of medical scientists who regard it as an irrational approach to health care; this view is shared by parts of the public.

## CAM research: more EU focus required

The European status of CAM is characterized by an enormous heterogeneity of and a lack of reliable data on all its aspects: use, provision, education, regulation, safety, and as regards the clinical topics of efficacy and effectiveness. This report summarises the key data that has been identified by the research programme, and finishes with a series of recommendations and a roadmap for future research into CAM.

## Project Rationale

### What is CAMbrella?

The CAMbrella project looks into the current situation of Complementary and Alternative Medicine in Europe. It has been working to establish sound knowledge of the core issues and current status of CAM in the EU.

### The aims of CAMbrella are to:

- create a knowledge base on patients' demand for CAM and the prevalence of its use in Europe
- review the current legal status of CAM in EU member and associated states
- explore the needs and attitudes of EU citizens with respect to CAM
- explore the providers' perspective on CAM treatments in the EU
- consult the global dimension of CAM research and development strategies
- propose an appropriate strategy to help develop an understanding of CAM use and its effectiveness in response to the needs of health care funding bodies, providers and patients
- facilitate and foster sustainable, high quality collaboration and networking of European CAM researchers.

### Methodology

These aims have been pursued in eight work packages and have resulted in a series of research papers and work package reports that reflect the current knowledge in the field. These as well as all other products generated by the project will be published on the website: [www.cambrella.eu](http://www.cambrella.eu). Research papers also will be published in scientific journals. Methods applied were systematic literature reviews, workshops, interviews and consensus meetings.

### Geographical scope

The project was intended to review the situation in the 27 EU member states plus the 12 associated countries.

## Key findings: The citizens' perspective

It was only possible to study 18 of the 39 member states and associated countries, due to a lack of data in the remaining 21. Substantial research-based knowledge about the needs of citizens with respect to CAM is available only from the UK. Nevertheless, the following tendencies can be reported:

### **Citizens in the EU wish to have access to increased and diverse CAM provision**

Studies indicate that citizens wish CAM to be available as part of their normal health care, for example in hospital and general practice care. They also wish CAM provision to be delivered not only by medical doctors and/or doctors trained in CAM specialities, but also by CAM providers who have no biomedical training. There is a wish for more, and more diverse, CAM provision.

### **Barriers in the access to CAM**

EU citizens also seem to meet considerable barriers in the access to CAM: CAM treatments are predominantly paid for privately and are difficult to access due to lack of availability and limited accessibility.

### **Citizens express a wish for more support and information regarding CAM from the medical professionals**

CAM use is often not disclosed by patients in other treatments (especially cancer treatment) because of the assumed or known hostile attitude of the medical professionals towards CAM treatments.

### **Citizens need easily accessible and trustworthy information**

European citizens wish to have access to reliable and trustworthy information that forms the basis for an informed decision about treatment options.

### **Citizens require transparent regulation of CAM practice and training**

Citizens' confidence in the provision of CAM is enhanced when CAM is provided within an existing framework such as general or hospital practice or when the practitioners are members of professional CAM organisations that ensure educational as well as ethical standards.

## Prevalence of CAM in the EU

### There is a lack of reliable data on the prevalence of CAM

While there are a few rigorous prevalence studies that are based on nationally representative samples, the vast majority are small and of poor quality. Most EU countries do not have any data at all. Reported prevalence rates of CAM use were between 0.3% and 86%.

Use of herbal medicine was the most frequently reported use of CAM. Musculoskeletal problems were the most reported condition.

Disappointment with Western medicine was a main reason for CAM use, although it is not possible to derive definitive conclusions due to the small numbers of studies reporting this data.

## Provision and regulation in the EU

Both medical and non-medical practitioners play an important role in the provision of CAM within the healthcare system in Europe.

CAM provision in the EU27+12 is maintained by more than 150,000 registered medical doctors (MDs) with additional CAM certification and more than 180,000 registered and certified non-medical CAM practitioners. This suggests up to 65 CAM providers (35 non-medical practitioners and 30 physicians) per 100,000 inhabitants, compared to the EU figures of 95 general medical practitioners per 100,000 inhabitants.

Acupuncture is the most frequently provided method (53% of all practitioners) with 80,000 physicians and 16,000 non-medical practitioners trained in the therapy, followed by homeopathy (27% – 45,000 and 4,500, respectively). These two disciplines are both dominated by physicians. Herbal medicine and reflexology are almost exclusively provided by non-medical practitioners.

Naturopathy, on the other hand, is dominated by 15,000 (mostly German) physicians, as is anthroposophic medicine (4,500) and neural therapy (1,500).

**No common approach can be identified as regards the provision of CAM practice in Europe.**

Each of the 39 countries studied has its own approach. Teaching and certification are subject to international, national or in some countries even regional regulations. The lack of coherence in training, education and provision of CAM was stressed throughout almost all aspects of the project and in all stakeholder and expert meetings.

**No common approach can be identified as regards the regulation of CAM practice in Europe.**

The regulatory environment determines how a provider can be educated, certified and offer services. There is a huge variety in regional, national, European and international legal regulations, which make any comparison of CAM practice and provision in any respect almost impossible. Although diversity in healthcare regulation enables a wider choice of options with regard to CAM aspects of health care, the same diversity seriously hampers any efforts to establish EU-wide predictable conditions for both treatment and research.

## Industry in the EU

Most CAM provision is 'hands-on' and/or consultative, without substantial turnover in medicinal products or equipment. The largest industry is probably in herbal and homeopathic products.

There are no clear figures about the whole pharmaceutical market for CAM related products. IMS Health gives an estimate of approximately €6 billion for the European share of global market of herbal medications in 2010, which is estimated at more than €11 billion.<sup>1, 2</sup>

As regards homeopathic medicinal products, the EU market represents about 0.7 % of the European pharmaceutical market, generating about €1.035 billion (ex-factory prices) in 2010 (ECHAMP 2011<sup>3</sup>).

1 IMS Health, 2010 – ref. by Busse, Werner R.

2 Herbal supplements and remedies – a global strategic business report. Global Industry Analysts, Inc, March 2012: [http://www.strategyr.com/Herbal\\_Supplements\\_and\\_Remedies\\_Market\\_Report.asp](http://www.strategyr.com/Herbal_Supplements_and_Remedies_Market_Report.asp)

3 ECHAMP – European Coalition on Homeopathic and Anthroposophic Medicinal Products

## Legislation in the EU

19 of the 39 countries have a general legislation for CAM, of which eleven have a specific CAM law and eight have sections on CAM included in their health laws (such as 'Law on health care' or 'Law on health professionals'). In addition to general CAM legislation, some countries have regulations on specific CAM treatments.

### Obstacles for patients

When patients cross borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers, who in addition tend to work under completely different reimbursement systems. This situation influences CAM patients' rights, access and potential safety, and constitutes a challenge to a harmonized national and European follow-up of the new patients' rights according to the cross-border health care Directive 2011/24/EU. (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>)

### Obstacles for practitioners

When practitioners cross borders they will encounter a substantial variety of CAM practice in Europe. While CAM professions in some countries are tightly regulated, the same professional categories in other countries are totally unregulated, meaning that it is almost impossible to establish professional common ground.

### Obstacles for researchers

When researchers cross borders they will experience that research on efficacy and effectiveness of CAM is severely hampered by the heterogeneity of European regulations. Practices and practitioners are not comparable across national boundaries, and any observational or experimental study can therefore be generalised only within a narrow national or cultural context.

## An economic perspective

Not much is known about the cost effectiveness of CAM provision in the EU. The scarce data (mostly from Switzerland and the UK) suggest that a consultation with a medical doctor in classical homeopathy can save approximately 15% cost on the cost of standard care. Despite more frequent and longer consultations and thus higher direct costs, the favourable result is achieved by lower indirect costs including the lower costs of the drugs, less time off work and in hospital care, and better quality of life.

## An EU Roadmap for CAM

The main goal of CAMbrella is to propose an appropriate strategy to help develop an understanding of CAM use and its effectiveness in response to the needs of health care funding bodies, providers and patients. The following 'EU Roadmap for CAM' is based on the output of all the work packages, including a systematic literature review of papers from 1990-2010. These resulted in the following findings:

- Knowledge about the prevalence of use of CAM in Europe is limited. Further population based research is urgently needed.
- Knowledge about the needs and attitudes of EU citizens, patients and providers is generally unsatisfactory.
- Public understanding of CAM and its potential is diverse across Europe, ranging from minimal knowledge to a well-informed general public.
- There is only limited valid data about the extent of CAM provision.
- Valid data about safety and adverse effects of CAM provision are generally unsatisfactory in Europe.
- The majority of clinical trials in the past have assessed the efficacy rather than the effectiveness of CAM, meaning there is a lack of data on the clinical outcomes of CAM treatments in comparison with conventional treatments.
- Past research pointed to the significant value of unspecific effects in CAM treatments, although this is also true for conventional medicine.

### **Consequently the challenges are to:**

- get essential information about the real situation as regards provision, use and regulation of CAM in all countries of Europe
- address the needs and attitudes of EU citizens, patients and providers
- create a valid knowledge data base on CAM safety in Europe
- establish scientific knowledge that is useful for all stakeholders including policy makers, researchers, health care providers and citizens.

A further input to the final recommendations for a coherent European strategy came from the analysis of global research and development strategies in CAM. This was achieved through an analysis of the positions of international stakeholders in this field and some interviews with selected stakeholders, including Ayush in India (regulatory body for Ayurvedic medicine) and NCCAM (National Center for CAM in the US, part of the National Institute of Health). This showed clearly that Europe lags well behind other regions such as North America or Asia in terms of the level of investment in CAM research and the integration of research results into health policy and health regulation.



## Conclusions and recommendations

### 1. CAM is a neglected area of research – it needs active encouragement

As the CAM industry is small, there are no major financial or/and industrial interests driving research efforts in this field. Scientific biases hamper the free exchange of ideas, concepts, treatment techniques and comparison of clinical outcomes. CAM is organised mostly in private provider settings (medical and non-medical), thus the academic experience among CAM providers is scarce and there are few academic centres of research, resulting in a substantial lack of funding for research programmes. Career opportunities in an academic setting are rare.

In order to pay proper attention to the real situation of use and provision of CAM in Europe, active encouragement to research on all levels is needed: private, university bound, national and European.

### 2. Research methods must reflect the real-world-settings of health care in Europe

CAM should be considered along the same scientific lines that apply to medical research in general. In recent years, a shift can be noticed from the testing of specific mechanisms in the efficacy of drugs and treatments to a more clinical approach to outcomes relevant to patients. Scientific discussion focuses increasingly on research frames that better reflect the 'real world' setting of medical and health care.

This shift is in line with the change from isolated efficacy research to more comparative effectiveness research, a research strategy designed to focus on competing treatment strategies in regard to their clinically relevant outcomes. The strategy for the investigation of CAM should include a broad range of mixed-method research strategies including comparative effectiveness research, qualitative and quantitative designs.

#### **Specifically, we recommend to:**

- establish a European-wide methodology including a monitoring or registration system, clinical trials including observational and comparative effectiveness research studies of different treatment strategies (CER designs); single case studies or case histories should be implemented to investigate safety aspects of CAM
- support and implement comparative effectiveness research and health economic evaluation in CAM
- address context and meaning factors (generally known as non-specific effects and may include the 'placebo effect') such as preferences and expectations in clinical research.

**3. An EU research strategy for CAM must prioritise a European wide approach that reflects the needs of the citizens and providers of CAM**

**An EU research strategy for CAM must:**

- establish a European-wide approach to assess the prevalence of use of core CAM treatment modalities
- determine how best to disseminate scientifically sound information about CAM to the European public, in line with the EU objective to enhance the ability of citizens to make better and informed decisions about their health care
- identify the most promising CAM treatment options for the most prevalent health conditions in Europe (obesity, chronic diseases like diabetes, cancer, musculoskeletal problems, healthy ageing and many others)
- quantify the economic effects of CAM in European health care
- evaluate patients' needs in particular in relation to safety issues
- carry out an evaluation of the chances and risks of structural integration of CAM into routine care programmes
- address the diversity of training, education and provision of CAM across Europe.

**4. A centralised and academically supported EU CAM centre should make this EU research strategy operational**

There is a widely recognised need to ensure high quality research, information and above all, effective dissemination of knowledge that is considered adequate for informed decision making by both providers and patients of CAM. All working groups of CAMbrella, as well as the EU health and international stakeholders, including citizens and patients, identified the regulatory and educational chaos as regards CAM provision.

There was a common recommendation for the establishment of an EU centre for CAM that looks into the situation of CAM and gives research-based guidelines on how to address it.

Such an EU CAM research centre would be regulatory- as well as research-oriented. It would serve as a trustworthy EU-centred body for any questions about CAM. Its objectives should reflect the research and development strategies in extra-European environments in terms of how to set priorities for CAM R&D topics and how to conduct CAM R&D.

## Recommendations for Policy Makers – CAMbrella calls on:

**the Members of the European Parliament, the European Commission, and the national health and research policy makers:**

to develop and implement a coherent CAM research strategy based on the findings of this study, through the establishment of a European centre for CAM, the purpose of which will be to:

- establish a European-wide approach to assess the prevalence of use of core CAM treatment modalities
- determine how best to disseminate scientifically sound information about CAM to the European public, in line with the EU objective to enhance the ability of citizens to make better and informed decisions about their health care
- identify the most promising CAM treatment options for the most prevalent health conditions in Europe (obesity, chronic diseases like diabetes, cancer, musculoskeletal problems, healthy ageing and many others)
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- evaluate patients' needs in particular in relation to safety issues
- carry out an evaluation of the chances and risks of structural integration of CAM into routine care programmes
- address the diversity of training, education and provision of CAM across Europe.

**DG Sanco and DG Research to enhance the efforts for adequate CAM research by:**

- providing fair chances in research programmes and calls for adequate and modern research methodology
- acknowledging various study designs (single case, observational studies, comparative effectiveness studies, randomized trials) depending on the research question.

**The European Commission DG Research and Innovation**

to recognise and give priority in Horizon 2020, the Framework Programme for Research and Innovation, under its focus on 'Health, demographic change and wellbeing,' to research into CAM and the implementation of the above recommendations.

Project Identity	HEALTH-F2-2009-241951
Coordinator	Competence Centre for Complementary Medicine and Naturopathy (CoCoNat), Klinikum rechts der Isar, Techn. Univ. Munich, Germany
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