ejom
Vol.7. No.6. 2014

Creative Interchange

The CAMbrella Initiative
What's happening across the European Union in the field of CAM provision and research

George Lewith and Andrew Flower

ABSTRACT
There is a pressing need for us to engage with the broader European context to ensure our traditional medicines survive and flourish. An essential part of this process is to familiarise ourselves with what is actually happening within the European Union (EU), regarding complementary and alternative medicines (CAM) in general, and Oriental medicine (OM) in particular. What constitutes CAM? Who is using it, delivering it, researching it and what are the legislative frameworks that currently govern its practice? It is only by gathering this basic information that we can understand the current status of CAM and OM and start to compose a coherent strategy to inform any future developments.

INTRODUCTION
'No man is an island, Entire of itself, Every man is a piece of the continent, A part of the main. … And therefore never send to know for whom the bell tolls; It tolls for thee.'

If we take the liberty of replacing the word 'man' with the unisex 'OM practitioner' then, despite the damage done to 17th century literature, John Donne's famous Meditation becomes very apt for all of us who read this European journal and operate in a European context. The 'tolling bell' of our connection to Europe is undeniable and has resulted in some fairly major changes in our medical practice.

In recent years the impact of the EU on OM has frequently been perceived as predominantly negative and restrictive. For many OM practitioners the EU Traditional Medicines legislation has had a fairly devastating effect on the availability of prepared herbal products used extensively in the past by herbalists and acupuncturists alike. Most patent remedies are now no longer available over the counter or even to qualified practitioners and the process of licensing new products is painstakingly slow, expensive and bureaucratically complex.

However our interactions with the EU have not been unremittingly negative. A three-year EU funded research project looking at good practice in traditional Chinese medicine (GP-TCM) engaged more than 200 scientists and clinicians from 112 institutions in 24 countries in discussions on good practice issues related to various aspects of Chinese herbal medicine and acupuncture research, leading to state-of-the-art reports and open access guidelines published in the Journal of Ethnopharmacology (Flower, 2011).

Perhaps the most basic and important lesson to be learnt from these examples is that we have to engage with the broader European context to ensure our traditional medicines survive and flourish. An essential part of this process is to familiarise ourselves with what is actually happening within the EU, regarding CAM in general, and OM in particular. What constitutes CAM? Who is using it, delivering it, researching it and what are the legislative frameworks that currently govern its practice? It is only by gathering this basic information that we can understand the current status of CAM and OM and start to compose a coherent strategy to inform any future developments.

CAMbrella
Fortunately much of this work has recently been undertaken by CAMbrella, an EU funded project that investigated the situation of CAM in Europe in 2012. CAMbrella encompassed 16 academic research groups (Table 1) from 12 European countries (Figure 1) and ran for 36 months starting from January 2010. The acronym brings together the terms 'CAM' and 'umbrella' to stress the project's effort both to harmonise existing knowledge and to determine the knowledge gaps in this field. Both parts come together in recommendations to the European Commission and the European Parliament on the way forward in Europe for research into CAM – the 'Roadmap for European CAM research'. The European Commission took the decision to fund this project under the 7th Framework Programme (FP7) because to date there has been no proper evaluation of the situation of CAM in Europe: this applies to almost all member and associate EU countries, with the noticeable exceptions of the UK, Switzerland and Norway. No other countries have investigated the topic, nor has the European Commission, i.e. Directorates-General Research and Health (Weidenhammer, 2011).

CAMbrella has sought to establish a scientific base from which to answer questions such as:

- What is CAM in Europe?
- Where do we stand with regard to CAM?
- What do citizens and patients expect as potential CAM users?
- What are the national and European regulatory settings of CAM?
- How are the safety needs of patients and citizens met?
- What is the situation with respect to freedom of informed choice in healthcare for European citizens; are their wishes taken into account by regional, national and European regulations?
- Who practises and provides CAM and how does education in CAM work?
- How is the European research and practice environment situation viewed by experts in the field outside the EU, for instance from the USA, India and China?
- Where should Europe go in terms of a co-ordinated CAM research strategy?

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The work packages (WP)
In order to achieve these aims CAMbrella was divided into eight work packages which are clearly described in Table 2. Summaries of each of the conclusions of the work packages are provided; individual papers are referenced for each work package and full reports are available free of charge from www.cambrella.eu

WP1: Terminology and definitions of CAM methods
The terms used for defining CAM including the methods, procedures, or therapies vary greatly. We explored the existing CAM terminologies to develop a Europe-wide and pragmatic definition of CAM which can be used to systematically research the prevalence, attitudes to and legal status of CAM in Europe. Terms and definitions were collected from scientific and non-scientific sources. They were analysed and discussed among the CAMbrella participants on several occasions with the aim of developing a better definition appropriate for Europe through consensus in a multi-step Delphi-process. This resulted in a pragmatic proposal for a European definition of CAM:

‘Complementary and Alternative Medicine (CAM) 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 has been mainly used outside conventional healthcare, but in some countries certain treatments are being adopted or adapted by conventional healthcare.’

Developing a uniform, pragmatic pan-European definition of CAM was complicated by a number of factors. These included the vast diversity of existing definitions, systems, disciplines, procedures, methods and therapies available within the EU as well as use of the same terms quite differently both within the EU and in comparison to the US and other parts of the world (Falkenberg, 2012).

WP2: Legal status and regulations
Aimed to review the legal and regulatory status of CAM in the 27 EU member states and 12 associated states. Contact was established with national ministries of health, law or education, members of national and European CAM associations, and CAMbrella partners. A literature search was performed in governmental and scientific/non-scientific websites as well as the EUROPA and EUR-lex websites/ databases to identify documents describing national CAM regulation and official EU law documents. The 39 nations have all structured legislation and regulation differently: 17 have a general CAM legislation, 11 of these have a specific CAM law, and 6 have sections on CAM included in their general healthcare laws. Some countries only regulate specific CAM treatments. CAM medicinal products are subject to the same market authorisation procedures as other medicinal products with the possible exception of

documentation of efficacy. The directives, regulations and resolutions in the EU that may influence the professional practice of CAM will also affect the conditions under which patients are receiving CAM treatment(s) in Europe. There is extraordinary diversity with regard to the regulation of CAM practice, but not CAM medicinal products. This will influence patients, practitioners and researchers when crossing European borders. Voluntary harmonisation is possible within current legislation. Individual states within culturally similar regions should harmonise their CAM legislation and regulation. This might safeguard against over/under regulation at the national level (Wiesener, 2012).

WP3: Needs and attitudes of citizens

To safeguard citizens' rights concerning their healthcare choices it was critical to gain an overview of their attitudes and to understand their expectations and needs regarding CAM. A literature review was undertaken, based on systematic searches of the following electronic databases: PubMed, Web of Science, CINHAL, AMED, PsycINFO and PsycArticles; 189 articles met inclusion criteria. Articles were analysed thematically and their reporting quality assessed. Despite the limited availability of research-based knowledge we noted that many citizens hold positive attitudes to CAM and wish for increasing access to CAM provision. People wanted impartial, reliable and trustworthy information to support informed decision-making, and some people wanted greater support and involvement of biomedical healthcare professionals in facilitating their healthcare choices. While EU citizens valued distinct aspects of CAM practice, they are also critical consumers and support clear regulatory and educational frameworks to ensure the quality and safety of CAM provision and medicinal products. Further research is required on three main issues: i) how citizens across Europe obtain information about CAM and the needs they may have for reliable information; ii) the local national approach to accessing CAM and iii) citizens' perspectives on the quality of care and safety of CAM provision and products (Nissen, 2012).

WP4: CAM use – the patients' perspective

Studies suggest that CAM is widely used in the EU. We systematically reviewed data, reporting research quality and the prevalence of citizen CAM use by citizens in Europe; what it is used for, and why. We searched for general population surveys of CAM use using Ovid MEDLINE (R) (1948 to September 2010), Cochrane Library (1989 to September 2010), CINAHL (1989 to September 2010), EMBASE (1980 to September 2010), PsychINFO including PsychARTICLES (1989 to September 2010), Web of Science (1989 to September 2010), AMED (1985 to September 2010), and CISCOM (1989 to September 2010). Additional studies were identified through experts and grey literature. Cross-sectional, population-based or cohort studies reporting CAM use in any EU language were included. Data were extracted and reviewed by two authors using a pre-designed extraction protocol with quality assessment instrument. 87 studies were included. Inter-rater reliability was good (kappa =0.8). Study methodology and quality of reporting were poor. The prevalence of CAM use varied widely within and across EU countries (0.3 per cent to 86 per cent). Prevalence data demonstrated substantial heterogeneity unrelated to report quality so we were unable to pool data for meta-analysis. Our summary data are based on descriptive statistics. Herbal medicine was the most commonly reported intervention. CAM users were mainly women. The most common reason for use was dissatisfaction with conventional care. CAM was widely used for musculoskeletal problems. True CAM prevalence across the EU is problematic to estimate because studies are generally poor and heterogeneous. A consistent definition of CAM, a core set of CAMs with country-specific variations and a standardised reporting strategy to enhance the accuracy of data pooling would improve reporting quality (Eardley, 2012).

WP5: CAM use – the providers' perspective

The demand for CAM treatment in the EU has led to an increase in the various CAM interventions (and practitioners) available to the public. Our aim was to describe the CAM services available from both registered medical practitioners and registered non-medical practitioners. Our literature search comprised a PubMed search of any scientific publications, secondary references, grey literature, personal communications and a search of government websites and websites of CAM organisations to collect data in a systematic manner. Different data sources had variable reliability so a classification was developed and implemented. These 'weighted databases' were condensed into tables and maps to display the provision of CAM disciplines by country, showing the distribution of CAM providers across countries. Approximately 305,000 registered CAM providers can be identified in the EU (about 160,000 non-medical and about 145,000 medical practitioners). Acupuncture (n = 96,380) is the most available therapeutic method for both medical (80,000) and non-medical (16,380) practitioners, followed by homoeopathy (45,000 medical and 5,800 non-medical practitioners). Herbal medicine (29,000 practitioners) and reflexology (24,600 practitioners) are mainly provided by non-medical practitioners. Naturopathy (22,300) is dominated by 15,000 (mostly German) doctors. Anthroposophic medicine (4,500) and neural therapy (1,500) are practised by doctors only. CAM provision in the EU is very variable in its national regulatory

management, which makes any direct comparisons across the EU almost impossible. Harmonisation of legal status, teaching and certification of expertise for therapists would be of enormous value (von Ammon, 2012).

WP6: CAM use – the global perspective

Our mission was to analyse global research and development (R&D) strategies for traditional medicine (TM) and complementary and alternative medicine (CAM) worldwide to learn from previous and on-going activities. Within CAMbrella, 52 representatives nominated 43 key international stakeholders (individuals and organisations) and 15 of these were prioritised. Information from policy documents including mission statements, R&D strategies and R&D activities were collected in combination with personal interviews. Data were analysed using the principles of content analysis. Key stakeholders vary greatly in terms of capacity, mission and funding source (private/public). They ranged from only providing research funding to having a comprehensive R&D and communication agenda. A common shift in R&D strategy was noted; ten years ago research focused mainly on exploring efficacy and mechanisms, today the majority of stakeholders emphasise the importance of a broad spectrum of research, including methodologies exploring context, safety and comparative effectiveness. The scarce public investment in this field in Europe stands in stark contrast to the large investments found in Australia, Asia and North America. There is an emerging global trend supporting a broad research repertoire, including qualitative and comparative effectiveness research. This trend should be considered by the EU given the experience and the substantial research funding committed by the included stakeholders. To facilitate international collaborative efforts and minimise the risk of investment failure, we recommend the formation of a centralised EU CAM research centre fostering a broad CAM R&D agenda (Hok, 2012).

WP7: Roadmap for future CAM research

Over the last two decades there has been a significant increase in CAM research publications but CAM research methodology has been heterogeneous and often of low quality. The aim of this systematic review was to investigate scientific publications with regards to their concepts, strategies, priorities and methods employed to evaluate the clinical and epidemiological research within CAM. We wanted to identify consensus-based research strategies. We performed a systematic literature search for papers published between 1990 and 2010 in seven electronic databases (Medline, Web of Science, PsychArticles, PsycInfo, CINAHL, EMBASE and Cochrane Library) in December 2010. In addition, experts were asked to nominate relevant papers. Inclusion criteria were publications dealing with research methodology, priorities or complexities in the clinical evaluation of CAM. From the 3,279 references identified from the search and 98 references contributed by CAM experts, 170 papers fulfilled our criteria and were included. The following key issues were identified: methodological difficulties in past CAM research (e.g., randomisation, blinding), the utility of quantitative and qualitative research methods in CAM, priority setting for CAM research and specific methodological issues regarding various CAM modalities. Most authors supported the use of commonly accepted research methods to evaluate CAM. There was broad consensus that a mixed methods approach is the most suitable for gathering conclusive knowledge about CAM (Fischer, 2012).

‘ The effects of meaning and context in both CAM and conventional medicine is very powerful and these issues need to be investigated carefully especially in long-term chronic conditions ’

The CAMbrella roadmap recommendations

Collecting and collating this data allowed us to develop a roadmap for future research. The findings of the CAMbrella project suggest six core areas for research to examine the potential contribution of CAM to the healthcare challenges faced by the EU. These areas include:

1. Evaluating the prevalence of CAM use in Europe, the EU citizens’ needs and attitudes regarding CAM and the safety of CAM.

2. The use of comparative effectiveness research methods is ideally suited to the clinical and health economic evaluation of

these therapies as an integrated addition to conventional care or in comparison to conventional care options.

3. The effects of meaning and context in both CAM and conventional medicine is very powerful and these issues need to be investigated carefully especially in long-term chronic conditions.

4. We need to explore the varied and different models for integrating CAM into existing healthcare systems on the basis of sound evidence. CAM research should use the same methods that are well validated and generally accepted in the evaluation of health services, including comparative effectiveness studies and mixed-methods designs.

5. A research strategy is urgently needed, ideally led by a European CAM co-ordinating research office dedicated to fostering systematic communication between EU governments, the public, charitable and industry funders, researchers, practitioner organisations, and other stakeholders.

6. A European Centre for CAM should ideally also be established to monitor and further a co-ordinated research strategy with sufficient funds to commission and promote high quality, independent research focusing on the public's health needs and pan-European collaboration. Table 2 indicates the major strategic recommendations that were arrived at by CAMbrella.

How can OM practitioners contribute?

This CAMbrella roadmap is both an exciting and a daunting prospect. It proposes complex, structural and potentially costly developments that do not appear to leave much space for individual practitioner input. However that is far from the case. There are a number of ways in which practitioners can make a useful contribution to this process.

One important 'way in' is to develop practitioner research networks. These could be facilitated by trained researchers who have an interest in a particular area of OM such as a specific disease like recurrent urinary tract infections, or in an aspect of treatment, such as the OM consultation process or the impact of pulse diagnosis on treatment outcome. Practitioner involvement could be limited to participating in a virtual or face-to-face survey or discussion, or could extend to treating and evaluating patients as part of a clinical trial. These networks could utilise practitioner expertise to ensure that research addresses 'real world' practice but also provide training in research methods or in the management of a disease that could really benefit the practitioner.

Another option for the practitioner who has undertaken or is considering an MSc course is to ensure that their dissertation is written up with an eye to being published in a peer reviewed journal. Methodologically rigorous research projects that focus on subjects ranging from systematic reviews of a particular disease to an in-depth analysis of a single case history could contribute to the evidence base for OM and possibly influence the direction of future research. Too often excellent and original work is filed, buried, and consigned to posterity!

Practitioners also need to encourage their professional associations to continue to invest in supporting research initiatives. These could involve, for example, arranging research related conferences, liaising with projects such as CAMbrella, subsidising seminars teaching critical appraisal skills, or providing bursaries for small-scale research projects.

Professional status, access to the herbal materia medica, and evaluation of safe and good practice depends upon research and we neglect it to our detriment. Individual practitioners and their collective organisations can become active stakeholders in the kind of developments identified by CAMbrella. This will help to ensure that strategic developments in the provision and research of OM are rooted in real life clinical practice.

CONCLUSION

CAMbrella has been an impressive pan-European fact-finding project that describes the current CAM 'scene' within the EU. Major differences in the use, delivery, research and regulation of CAM exist in member states. Considerable further investigation needs to be conducted to understand the complexities of the present situation and to help determine the future role for CAM within the EU. CAMbrella has identified a series of priorities that include adopting appropriate methodological approaches to CAM research, assessing risks and benefits from CAM treatments, and exploring how CAM could become more integrated within mainstream healthcare provided by each member state. It remains to be seen if the tolling bells of Europe are a warning of danger or a cause for celebration.

Table 1: List of co-operation partners forming the CAMbrella consortium
(*affiliated to university, [MB]member of Management Board, [SSC]member of Scientific Steering Committee)

Beneficiary name - short name	Country	Staff involved
1 Technische Universität München - Klinikum rechts der Isar (Coordinator) – MRI*	Germany	W. Weidenhammer[MB,SSC], M. Schagerl, S. Regenfelder
2 Wiener Internationale Akademie für Ganzheitsmedizin - GAMED	Austria	B. Reiter[SSC], S. Zopf
3 Universitetet i Tromsø – NAFKAM*	Norway	V. Fønnebø[SSC], S. Wiesener, L. Salomonsen
4 Universität Bern – UNIBE*	Switzerland	K. von Ammon[SSC], M. Frei-Erb
5 University of Southampton – US*	UK	G. Lewith[SSC], F. Bishop, S. Eardley, M. Jong
6 Charité – Universitätsmedizin Berlin – Charité*	Germany	B. Brinkhaus[MB,SSC], D. McBride, F. Junne, F. Fischer
7 Universität Zürich – UZH*	Switzerland	B. Uehleke[SSC], J. Melzer, H-W. Hoefert
8 Comitato Permanente di Consenso e Coordinamento per le Medicine Non-Convenzionali in Italia – ComCAM	Italy	P. Roberti di Sarsina, I. Iseppato
9 Karolinska Institutet – KI*	Sweden	T. Falkenberg[SSC], J. Hoek
10 Université Paris 13 – SMBH*	France	G. Delahaye, P. Escure, A. Lazarus
11 Servicio Andaluz de Salud – SAS	Spain	J. Vas, K. Santos Rey
12 Agenzia sanitaria e sociale regionale – Regione Emilia-Romagna - ASSR	Italy	F. Cardini, S. Florindi
13 Pécsi Tudományegyetem – University of Pecs – PTE*	Hungary	G. Hegyi
14 Universitatea de Medicina si Farmacie Victor Babes Timisoara – UMFT*	Romania	S. Dragan, S. Ursoniu
15 Syddansk Universitet – SDU*	Denmark	H. Johannessen[SSC], N. Nissen, J. Sorensen, J. Madsen
16 Bayerische Forschungsallianz gemeinnützige GmbH – BayFOR	Germany	F. Baumhöfener[MB], M. Dlaboha[MB]

Table 2: Brief description of the objectives of CAMbrella Work Packages 1 to 9, (L) indicates the Work Package leader position

WP1: Terminology and definitions of CAM methods

Work group members: UZH (L), US, ComCAM, KI, SMBH, SAS
- Identifying and analysing the existing terms and definitions of CAM used in scientific publications.
- Providing a core set of CAM disciplines and methods being used consistently all over Europe and an additional list of country specific CAM disciplines and methods.
- Developing a proposal for a practical pan-European definition of CAM, its disciplines and respective methods.

WP2: Legal status and regulations

Work group members: NAFKAM (L), ComCAM, KI, SMBH, PTE

Report on the current status with respect to:
- legal status of CAM
- regulatory status and governmental supervision of CAM practices
- reimbursement status of CAM practices and medicinal products
- regulation of CAM medicinal products
- status of EU-wide regulation of CAM practices and medicinal products
- potential obstacles for EU-wide regulation of CAM practices and medicinal products.

WP3: Needs and attitudes of citizens

Work group members: SDU (L), GAMED, MRI, SMBH
- To identify cross-European indicators for population-based needs and attitudes regarding CAM.
- To identify and map the needs of European citizens with respect to CAM.
- To identify and map EU citizens' attitudes towards CAM.
- To provide information on citizens' needs and attitudes regarding CAM.

WP4: CAM use – the patients' perspective

Work group members: US (L), GAMED, NAFKAM, Charité, UZH, SAS, ASSR, PTE, UMFT
- Identify a standardised questionnaire for CAM use.
- Address the prevalence of CAM use in Europe.
- Identify the major conditions treated with CAM.
- Explore the reasons why patients choose CAM.

WP5: CAM use – the providers' perspective

Work group members: UNIBE (L), US, ComCAM, ASSR, PTE, UMFT, SDU

To identify the different models of CAM provided in European public health systems:
- by registered physicians and CAM practitioners
- by country
- in relation to other international perspectives.

WP6: CAM use – the global perspective

Work group members: KI (L), MRI, NAFKAM, US, SAS
- To incorporate experiences from countries in which CAM R&D is integrated and publicly supported (US/Canada), while exploring its use as traditional medicine in developing countries.
- To understand the pros and cons of CAM R&D internationally addressing issues of patient rights and needs, cost, regulation, evidence base and research policy/strategy.
- To investigate risks of over-harvesting medicinal plants, and protection of traditional inherited knowledge of traditional medicine used within CAM.
- To identify the R&D strategies to be addressed from an EU perspective.

WP7: Roadmap for future CAM research

Work group members: Charité (L), MRI, NAFKAM, UNIBE, US, UZH, ASSR, SDU
- Analysis of the research methods already used to identify prevalence and use of CAM in the EU.
- Develop research methods and strategies for CAM that take into account the needs and attitudes of EU citizens and providers (funders and clinicians).
- Develop research strategies and a roadmap to enable future CAM research regarding effectiveness, efficacy, cost effectiveness and safety.

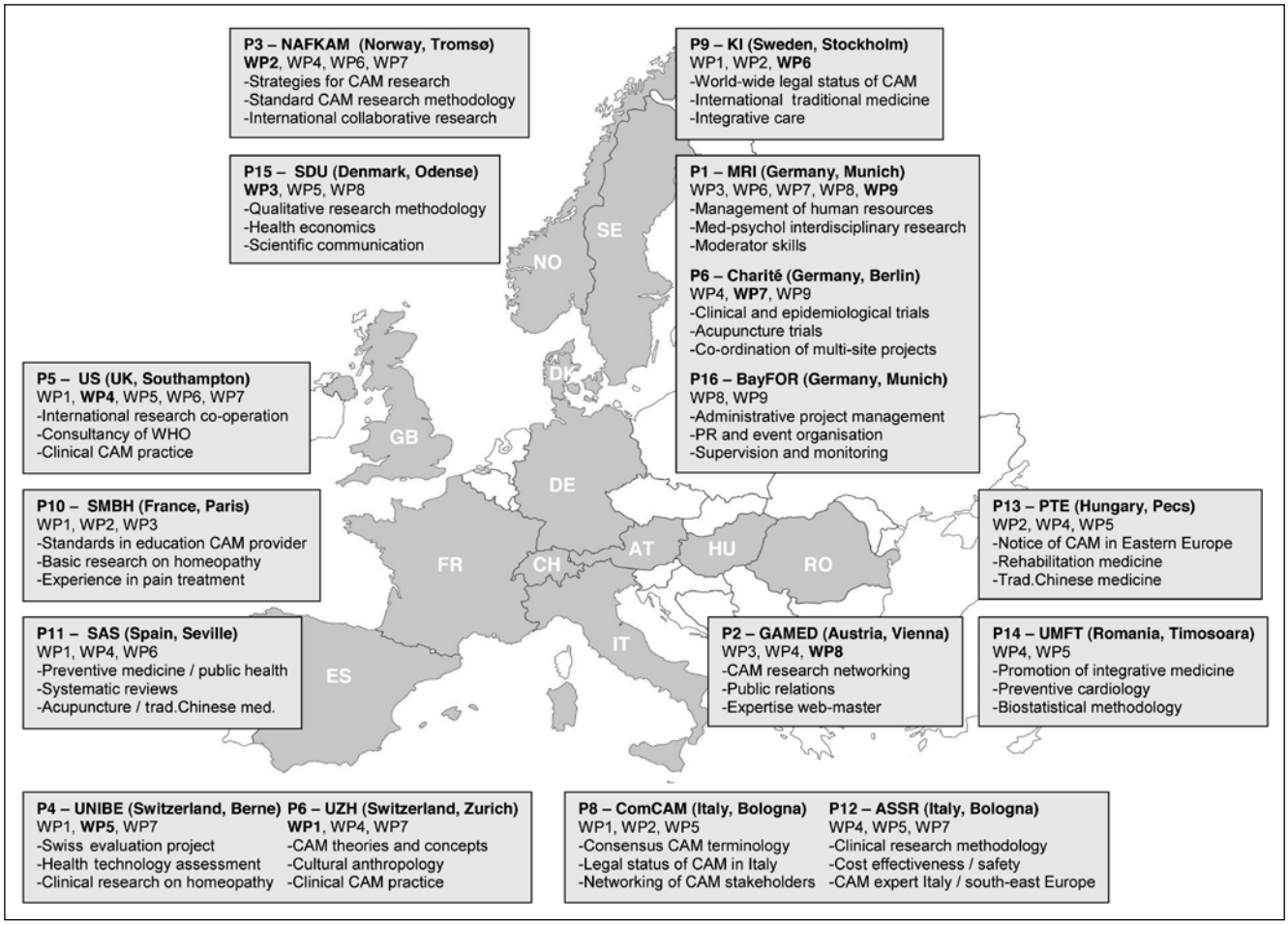
WP8: Dissemination and communication

Work group members: GAMED (L), MRI, SDU, BayFOR
- To foster project internal communication and external communication with CAM stakeholders including patient and public healthcare organisations.
- To establish, host and maintain a website as the common platform for CAMbrella (www.cambrella.eu).
- To identify CAM stakeholders and appropriate target audiences in Europe through which to disseminate information generated by the project.
- To plan and organise the final CAMbrella conference.

WP9: Management

Work group members: MRI (L), Charité, BayFOR
- To ensure smooth and efficient project implementation and achievement of all project objectives.
- To provide daily co-ordination and management for the entire project.
- To provide administrative support to all participants.
- To ensure financial regularity and ethics compliance.
- To identify obstacles to running and managing the project (risk management).
- To ensure sustainability of the established network.
- To report to the European Commission.

Figure 1



Tables 1, 2 and Figure 1 reproduced from:

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