



DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT
ECONOMIC AND SCIENTIFIC POLICY **A**

Economic and Monetary Affairs

Employment and Social Affairs

**Environment, Public Health
and Food Safety**

Industry, Research and Energy

Internal Market and Consumer Protection



Complementary and Alternative Therapies for Patients Today and Tomorrow

Study for the ENVI Committee

DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

Complementary and Alternative Therapies for Patients Today and Tomorrow

Brussels, 16 October 2017

PROCEEDINGS

Abstract

This report summarises the presentations and discussions of a workshop on “Complementary and Alternative Therapies for Patients Today and Tomorrow”, held at the European Parliament in Brussels on Monday 16 October 2017. The aim of the workshop was to provide background and technical information and advice to the members of the ENVI Committee on the latest findings and trends in the field of complementary and alternative therapies.

The current state of play of complementary and alternative therapies in Europe was highlighted during the first part of the workshop. Presentations focused on CAM in practice and academic research.

The second part of the workshop focused on the policy and legal framework in Europe and the integration of CAM into EU healthcare systems.

This document was requested by the European Parliament's Committee on Environment, Public Health, and Food Safety.

CONTRIBUTING EXPERTS

MEP Ms Soledad CABEZÓN RUIZ, co-Chair ENVI Health Working Group

MEP Mr Alojz PETERLE, co-Chair ENVI Health Working Group

Dr Ton Nicolai, EUROCAM Spokesperson

Dr Wolfgang Weidenhammer, Technische Universität München, Germany

Ms Agnes Mathieu-Mendes, European Commission, DG SANTE, Deputy Head of Unit, Medical products: quality, safety, innovation

Dr Stéphane Espinosa, World Health Organization (WHO), Consultant in the Traditional, Complementary and Integrative Medicine (TCI) Unit in the Department of Service Delivery and Safety (SDS)

SUMMARY PREPARED BY

Ms Alexandra SCHNEIDERS

Mr Matteo MASCOLO

Ms Alicia MCNEILL

Ms Meena FERNANDES

Milieu Ltd, Brussels, Belgium

RESPONSIBLE ADMINISTRATOR

Mr Miklos GYOERFFI

EDITORIAL ASSISTANT

Ms Eva ASPLUND

ABOUT THE EDITOR

To contact the Policy Department or to subscribe to its monthly newsletter please write to:

Policy Department Economic and Scientific Policy

European Parliament

B-1047 Brussels

Poldep-Economy-Science@europarl.europa.eu

Manuscript completed in October 2017.

© European Union, 2017.

This document is available on the Internet at:

<http://www.europarl.europa.eu/supporting-analyses>

LINGUISTIC VERSION

Original: EN

DISCLAIMER

The opinions expressed in this document are the sole responsibility of the author and do not necessarily represent the official position of the European Parliament.

Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the publisher is given prior notice and sent a copy.

CONTENTS

LIST OF ABBREVIATIONS	4
EXECUTIVE SUMMARY	5
EU POLICY CONTEXT	7
PROCEEDINGS OF THE WORKSHOP	10
1.1. Introduction	10
1.1.1. Welcome and opening	10
1.2. Part I: The current state of play of complementary and alternative therapies (cam) in Europe	10
1.2.1. Overview of CAM therapies in Europe	10
1.2.2. The status of research on CAM across the EU	12
1.2.3. Questions & Answers	13
1.3. Part II: Traditional, complementary and alternative medicine: Policy and public health perspectives	14
1.3.1. The legal and policy framework of CAM in Europe	14
1.3.2. Integrating CAM into EU healthcare systems	16
1.3.3. Questions & Answers	18
1.3.4. Closing remarks by the Chair	18
ANNEX 1: PROGRAMME	20
ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS	21
ANNEX 3: PRESENTATIONS	23
Presentation by Ton Nicolai	23
Presentation by Wolfgang Weidenhammer	33
Presentation by Agnes Mathieu-Mendes	43
Presentation by Stéphane Espinosa	49

LIST OF ABBREVIATIONS

CAM	Complementary and alternative therapies
DG SANTE	Directorate General for Health and Food Safety
EC	European Commission
EP	European Parliament
EU	European Union
GP	General Practitioner
MEP	Member of European Parliament
MS	Member States
T&CM	Traditional and complementary medicine
WHO	World Health Organisation

EXECUTIVE SUMMARY

On 16 October 2017, the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) held a workshop on "*Complementary and alternative therapies for patients today and tomorrow*". The workshop was hosted by Ms Soledad CABEZÓN RUIZ (MEP) and Mr Alojz PETERLE (MEP), Co-Chairs of the Health Working Group within the ENVI Committee.

The Chair, Mr Peterle, opened the workshop by highlighting that the acceptance of complementary and alternative therapies (CAMs) varies across the EU Member States (MS). This creates barriers which reduce the accessibility of patients to CAMs. Mr Peterle stated that if a level playing field can be achieved between MS, then the freedom of movement of drugs, practitioners and patients will be facilitated. The Co-Chair, Ms Cabezón Ruiz, stated that three issues should be discussed during the workshop: the requirements that should be prioritised when considering CAMs; scientific evidence regarding their effects; and how they should be regulated.

The first part of the workshop focused on the current state of play of complementary and alternative therapies in Europe. Dr NICOLAI, EUROCAM Spokesperson, opened the session by providing an overview of CAMs in Europe. He started his presentation by describing the increasing demand for CAMs in Europe, with one out of two European citizens using CAMs either by consulting CAM professionals or purchasing CAMs-related products. Furthermore, he explained that a growing number of conventional doctors are referring patients to CAM professionals. Hospitals are also offering integrated solutions with CAM options. Further, Dr Nicolai remarked the fragmentation within the EU as regards CAM recognition and regulation. He finalised his presentation by emphasising the fundamental differences between conventional and CAM therapies. Dr Nicolai highlighted that the two systems should be interwoven, bearing in mind the crucial role played by conventional medicine when it comes to treating life-threatening diseases.

Dr WEIDENHAMMER, Coordinator of the CAMbrella project, focused his presentation on the status of research on CAM across the EU. He began his presentation with an overview of the status of CAM research in terms of quantity and quality. With regard to quantity, he observed that there have been many improvements in the past 25 years as regards the amount of research carried out on CAM therapies. As regards the quality, he noted that studies must include a range of factors, such as the success rate of a particular therapy for different health conditions in order to be successful. Moreover, he described the complexity of study findings, with many producing inconclusive results that are subject to discussion. Lastly, he briefly presented the CAMbrella report, which was supported by the European Commission, and whose main aim was to assess the CAM field for future research at European level. He concluded his presentation by highlighting the importance of public funding for CAM research and by underscoring that research should also focus on medical practitioners' experiences with CAM therapies.

The second part of the workshop focused on the policy and public health perspectives of traditional, complementary and alternative medicine. Ms MATHIEU-MENDES, Deputy Head of Unit of Unit B.4. Medical products: quality, safety and innovation at the European Commission (DG SANTE), gave a presentation on the legal and policy framework of CAMs in Europe. She outlined the legislative framework of herbal and homeopathic medicines. She remarked that in 2004, new laws were drafted for the authorisation of these products that did not require clinical trials but instead proof of

use for 30 years and evidence of the medicine's benefits. However, she noted that companies find this system burdensome and continue to use the normal system of authorisation requiring clinical trials. She also stressed that companies choosing to register products as food additives further complicates the regulation of such products. The European Commission's aim for the coming years is to facilitate the implementation of the rules rather than to change them in order to ensure the safety of CAM products and their free movement in the EU.

The final speaker of the afternoon was Dr ESPINOSA, Consultant in the Traditional, Complementary and Integrative Medicine (TCI) Unit, at the World Health Organisation (WHO)'s Department of Service Delivery and Safety (SDS). He spoke about the integration of CAMs into EU healthcare systems. He emphasised the importance of integrating the benefits of the conventional and CAM medical approaches in the interest of patients, as well as the need for a dialogue between both sides. He also observed that alternative practice in one country may be considered as conventional in another country. However, all countries are united in their need for further research and guidance as to how CAM should be regulated and monitored. The WHO is therefore developing several guidance documents, some of which Dr Espinosa described, on how WHO MS can successfully introduce CAM into their healthcare services by ensuring the quality, safety and effectiveness of services.

In his closing remarks, the Chair Mr Peterle thanked the speakers and stressed the importance of the benefits that CAM therapies will bring to patients in the EU, namely a more varied choice of therapies. The discussion should not be dominated by setting the two ideologies, conventional and CAM, against each other, but rather by integrating them for the benefit of the patients.

EU POLICY CONTEXT

Complementary and alternative medicines (CAM) cover a variety of medical systems, products and practices that are usually not part of conventional health care¹. While grouped under the same definition, complementary and alternative medicines represent two different practices.

Complementary medicine refers to all treatments used alongside conventional medical treatments. For instance, acupuncture can support cancer treatment or yoga can reduce anxiety. Alternative medicine, on the other hand, comprises treatments that are used instead of standard medical treatments. One example is using a special diet to treat cancer instead of undergoing surgery prescribed by an oncologist².

In 2005, the World Health Organization (WHO) issued the Global Atlas of Traditional, Complementary and Alternative Medicine, a review-based overview of the status of CAM across the world. According to the study, chiropractic manipulation, homeopathy, phytotherapy/herbal medicine, and massage are among the most used CAM therapies³. In Europe, an increasing number of EU citizens are opting for CAM therapies to complement or treat their diseases⁴. The European Commission estimates that consumers' spending on CAM is almost EUR 100 million⁵.

The number of CAM-trained practitioners is also growing. In Europe, CAM is practiced by approximately 145.000 physicians (trained in both conventional medicine and CAM therapies), as well as more than 160.000 non-medical practitioners. These figures show that in Europe there are almost 65 CAM providers per 100.000 inhabitants⁶.

The growing use of CAM among European citizens and practitioners creates a regulatory challenge for the European Union. The regulation of CAM varies between MS with regards to its definition, the person entitled to practice it, the system of authorisations and reimbursement, and the resources to finance it. For example, in some countries, alternative therapies are provided outside conventional health care institutions, whereas in others they are provided as part of conventional health care services. Moreover, in some MS, CAM can only be provided by medical practitioners, whereas in others, non-medical practitioners may also provide certain alternative therapies. In addition some CAM health-related topics fall under the exclusive competences of the MS, which makes a harmonised approach even more difficult⁷. Together these factors create barriers which hamper the creation of a pan-European

¹ While CAM has been defined by the CAMbrella project, there is currently no globally accepted definition.

² Tabish, S. A., 2008, 'Complementary and Alternative Healthcare: Is it Evidence-based?' *International Journal of Health Sciences*, 2(1), V-IX, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068720/> (accessed August 2017).

³ Bodeker G, Ong CK, Grundy C, Burford G, Shein K, 2005, 'WHO Global Atlas of Traditional, Complementary, and Alternative Medicine', Kobe, Japan: World Health Organization, available at: http://apps.who.int/iris/bitstream/10665/43108/1/9241562862_map.pdf (accessed August 2017).

⁴ Frass, M., Strassl, R. P., Friehs, H., Müllner, M., Kundi, M., & Kaye, A. D., 2012, 'Use and Acceptance of Complementary and Alternative Medicine Among the General Population and Medical Personnel: A Systematic Review', *The Ochsner Journal*, 12(1), 45-56, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3307506/> (accessed August 2017).

⁵ European Commission, Cordis, official webpage, "Complementary medicine popular across Europe", available at: http://cordis.europa.eu/news/rcn/35388_en.html (accessed August 2017).

⁶ 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 (accessed August 2017).

⁷ Wiesener S., Falkenberg T., Hegyi G, et al., 2012, 'Legal status and regulation of CAM in Europe. Part I – CAM regulations in the European countries', Final report of CAMbrella Work Package 2, available at: http://www.cam-europe.eu/dms/files/CAMbrella_Reports/CAMbrella-WP2-part_1final.pdf (accessed August 2017).

Regulation of CAM professions, inhibit the development of cross-border research, and ultimately reduce accessibility of CAM to patients.

The European Union has taken several steps towards an EU-wide harmonisation of CAM therapies. In 1992, the EU issued Directive 92/73/EEC, the first legal instrument regulating CAM⁸, which was repealed in 2001 by the "[Homeopathic] Medicinal Products Directive"⁹. This Directive, together with the Herbal Medicine Directive¹⁰, aims to provide patients with enough information so as to ensure the safety and good quality of traditional medicinal products on the market. To this end, the Directives have introduced special authorisation and registration procedures for CAM products.

Furthermore, both the European Parliament¹¹ and the Parliamentary Assembly of the Council of Europe¹² have recommended a stronger harmonization of non-conventional medicine in Europe and have called upon MS to support comparative studies and research programmes on this matter.

In 2010 the CAM Interest Group was founded as an informal group of members of the European Parliament with a special interest in Complementary and Alternative Medicine. This Interest Group aims to put and keep CAM on the EU policy agenda, generate discussions and actions in that area, as well as to promote awareness about CAM and other holistic approaches¹³.

The EU has also provided funding opportunities to CAM research programmes. In 2012 the European Commission's Directorate-General for Research and Innovation founded the CAMbrella project: a three year survey of the status of CAM in Europe between 2010 and 2012¹⁴. The goal of the project was to develop a roadmap for future European research in CAM appropriate for the health care needs of EU citizen. The findings of the project were published in April 2013, and showed a lack of data concerning the efficacy of CAM treatments, as well as a lack of commonly agreed standards concerning definition, legal status, and provisions of CAM. The project also concluded that there is a lack of integration of CAM into national public health systems, as well as an inadequate availability of research facilities.

⁸ Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products, OJ L 297, 13.10.1992, p. 8–11, available at:

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31992L0073> (accessed August 2017).

⁹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67–128, available at:

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf (accessed August 2017).

¹⁰ Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136, 30.4.2004, p. 85–90, available at:

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2004_24/dir_2004_24_en.pdf (accessed August 2017).

¹¹ European Parliament, 1997, Resolution on the status of non-conventional medicine, available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A4-1997-0075+0+DOC+XML+V0//EN> (accessed August 2017).

¹² Council of Europe, Parliamentary Assembly of the, Resolution 1206(1999), A European approach to non-conventional medicines, available at: <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=16727&lang=en> (accessed August 2017).

¹³ Eurocam, official webpage, Cam Interest Group, available at: <http://www.cam-europe.eu/cam-interest-group-meetings.php> (accessed August 2017).

¹⁴ CAMbrella project, official webpage, available at: <http://www.cambrella.eu/home.php?> (accessed August 2017).

Internationally, the WHO's World Health Assembly adopted two resolutions in 2009 and 2014 respectively, urging countries to: i) integrate CAMs in national public health systems; ii) to promote the safety and quality of CAM; iii) to establish a system of qualification for CAM professionals; and iv) to increase the availability and affordability of CAM¹⁵.

Coordinated actions are thus critical to regulate CAM professions throughout the EU. The role of CAM should be taken into account throughout the entire health spectrum: from a general holistic perspective to CAM specific treatments. The process, in particular, should aim at fostering high quality research to obtain reliable information on CAM costs, safety and effectiveness, and supply the evidence base which would enables European citizens and policymakers to make informed decisions about CAM and ultimately integrate it into the EU and MS health policy agendas.

¹⁵ WHO's World Health Assembly, 2009, Resolution WHA 62.13 on Traditional Medicine, available at: <http://apps.who.int/medicinedocs/en/d/Js21477en/> (accessed August 2017); WHO's World Health Assembly, 2014, Resolution WHA 67.18 on Traditional Medicine, available at: <http://apps.who.int/medicinedocs/en/d/Js21462en/> (accessed August 2017);

PROCEEDINGS OF THE WORKSHOP

1.1. Introduction

1.1.1. Welcome and opening

MEP Mr Alojz PETERLE, Co-Chair, ENVI Health Working Group

Mr Alojz PETERLE, MEP, opened the workshop by welcoming those in attendance. He stressed the importance of considering the perspective of the patient, drawing on his own experiences as a cancer patient. He said that patients do not discuss the ideologies or differences behind treatments, but are merely interested in what treatments work best for them. He noted, however, that attitudes to complementary and alternative medicines (CAM) vary greatly between Member States (MS) in Europe. Patients and practitioners alike lament these differences, and this has led to calls for help from the EU institutions regarding the best therapies, products, and knowledge.

MEP Ms Soledad CABEZÓN RUIZ, Co-Chair, ENVI Health Working Group

Ms Soledad CABEZÓN RUIZ began her statement by recognising that the issue of CAM can be considered from two different perspectives. She noted that there are three basic issues that need consideration: the definition of CAM, especially given that there are more than 100 different types of CAM; the scientific evidence and how CAM can be regulated.

Mr Peterle then gave the floor to the first speaker.

1.2. Part I: The current state of play of complementary and alternative therapies (cam) in Europe

1.2.1. Overview of CAM therapies in Europe

Dr Ton NICOLAI, EUROCAM Spokesperson

Dr Ton NICOLAI began his presentation by addressing the question of what CAM is, and the benefits and limitations. He noted that CAM is a societal phenomenon throughout the western world, and its use has sharply increased in the last two decades. He attributed this to the increasing number of people who feel personally responsible for their own health, and who have holistic views. Such people, according to Dr Nicolai, are dissatisfied with conventional medicine and its unpleasant side effects and the (life)long regimes, opting instead for more gentle therapies. Dr Nicolai stated that half of all European citizens use CAM either by seeing a professional, or using over-the-counter remedies. Dr Nicolai noted that this figure is higher among those citizens suffering from chronic disease. Despite this, a CAMbrella survey of EU citizens showed that the majority of patients want conventional doctors to have more knowledge and advice regarding CAM.

Dr Nicolai then presented some figures – noting that in Europe there are 150,000 medical doctors with additional CAM qualification, and more than 180,000 CAM practitioners that do not have a full medical education. The most common treatments practiced by medical doctors are acupuncture, homeopathy, naturopathy, anthroposophic medicine, and neural theory. Those practicing without a full medical training provide mostly herbalism, manual therapies (osteopathy, chiropractic), reflexology, shiatsu, yoga, tai chi and qigong.

In Europe, Dr Nicolai mentioned, an increasing number of doctors are referring patients to CAM professionals, more hospitals provide integrated solutions with CAM, and CAM is playing a larger role in universities and education. Despite this, less than one third of EU MS have legislation on CAM in general. It must be noted that in some MS, CAM is included in health laws, and in some countries, no medicines are registered. This disparity is also reflected in the regulation of professionals. In some countries only doctors with CAM qualifications can provide such services, in others, anyone can practice.

Dr Nicolai then introduced several examples. He gave the context of a patient affected by highly virulent bacteria. In such a case, antibiotics will save his life. However, if a patient has recurrent but less serious infections, repeated antibiotic use will lead to antimicrobial resistance. Instead, the susceptibility of patients needs to be considered, as well as the role of CAM in diminishing susceptibility and enhance the patient's level of health and resilience.

In Dr Nicolai's second example, a patient suffering from asthma or migraines or hypertension may be prescribed the long-term use of convention prescription drugs, which are not an effective final solution. However, a CAM practitioner would look for whatever makes the patient susceptible to these illnesses.

Dr Nicolai then explained the difference between conventional and CAM approaches. The essential difference, according to Dr Nicolai, lies in the basic concepts of health and disease. In western biomedical science, the mind and body are separated, with the body considered a complex machine. Diseases therefore results from tissue or biochemical disruption, and treatment is a matter of combatting disease by intervening in the pathological process, using prescription drugs or surgery etc. Treatments are standardised, following protocols and guidelines, and doctors are primarily responsible for the patient, who passively receives treatment. Dr Nicolai noted that this approach has many benefits, from blood transfusions to vaccinations to the use of antibiotics and chemotherapy, but it also has disadvantages and limitations. Biomedicine usually manages symptoms of chronic diseases, rather than restoring patients. Prescription drugs are costly and many patients die from effects of them, or develop a life-long dependency.

On the other hand, the CAM model sees humans as adaptable, self-regulating, creative biological systems. Patients themselves take responsibility for their health, and care is individualised, with responsibility shared between physician and patient. Treatment includes mobilising and stimulating the self-regulating capacity, restoring the balance in the psychosomatic system with the eventual aim of creating and maintaining the health and wellbeing, and reinforcing the autonomy and resilience of the patient. Benefits of the CAM model include supporting and inducing cell-regenerating processes of the patient, which reduces the need for high-cost interventions. In addition, CAM is safe with hardly any effects, and a reduction in prescription drugs reduces the problems of dependency and antimicrobial resistance. CAM also has high patient satisfaction, increased quality of life and reduced cost. Yet, as Dr Nicolai pointed out, CAM is not without limitations. In the case of serious diseases like cancer, sepsis, etc., protection of life must always have priority over CAM. In addition, in a number of EU MS, CAM practices and medicinal products are unregulated and may pose risks to the health and safety of patients. Dr Nicolai stressed that CAM professionals should therefore be regulated, based on clearly defined qualifications and competences, as should CAM products.

Dr Nicolai concluded by saying that both models are needed to both fight and destroy the enemy and strengthen the home forces. There is a definite need for a balanced and collaborative approach. This approach has been growing in the US Academic Consortium for Integrative Medicine & Health in the US, which is made up of 70 highly esteemed academic centres, including Harvard Medical School, Yale University, Stanford University, Mayo Clinic, etc. Dr Nicolai noted that CAM should be included in all EU policies, and CAM products and services should be accessible and affordable for all EU citizens who wish to make use of it.

Dr Nicolai finished with a quote from Dr Margaret Chan, WHO Director-General 2006-2017. "The two systems of traditional and Western medicine need not clash. Within the context of primary health care, they can blend together in a beneficial harmony, using the best features of each system and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made...The time has never been better, and the reasons never greater, for giving traditional medicine its proper place in addressing the many ills that face all our modern – and our traditional – societies".

1.2.2. The status of research on CAM across the EU

Dr Wolfgang WEIDENHAMMER, Coordinator of the CAMBRELLA project

Dr Wolfgang WEIDENHAMMER began his presentation by stating that the status of CAM research, in terms of both quality and quantity, started off poor, but has gotten much better in the last 25 years. Despite this, there is still a need for improvement. Dr Weidenhammer presented a graph showing the number of publications in scientific medical papers in the past 25 years has increased at a satisfying rate. Despite this, this does not show the full picture. The question "does CAM work" cannot be answered – there are many different CAM models and hundreds of medical conditions where CAM methods claim to be beneficial, and all combinations should be explored in research. The field of research is large and complex, and made up of many elements, not least because patients may be using a combination of CAM.

Dr Weidenhammer took acupuncture as an example. He referenced a recent review of acupuncture¹⁶, which screened a total of 136 systematic reviews, covering more than 122 different medical conditions. This review included pooled data from more than 1,000 randomised controlled trials. The study built categories based on evidence levels. Out of 122 conditions, eight showed strong evidence of effect from acupuncture, 38 found moderate evidence. 71 showed unclear/mixed evidence. This last category is subject to scientific discussion. Some say this is proof of evidence, others say it is not. Dr Weidenhammer referred the audience to his slides (see Annex 3) for a list of the diseases affected (or not) by acupuncture.

Dr Weidenhammer then turned to the example of homeopathy¹⁷, which was subject to a similar study, looking at over 200 different trials. 41 trials found homeopathy was effective, however, the largest share of the results were inconclusive. Dr Weidenhammer noted that the situation can be seen either optimistically or pessimistically, however, it shows there is a need to review and process all the evidence.

¹⁶ McDonald J, Janz S. The Acupuncture Evidence Project: A Comparative Literature Review (Revised edition). Brisbane: Australian Acupuncture and Chinese Medicine Association Ltd; 2017.

¹⁷ <http://faculty.ofhomeopathy.org/research/>

Dr Weidenhammer then focused his presentation on the CAMbrella project. It was originally started in 2010 as a three-year project with financial support from the 7th Framework Programme. It was set up as a coordination action, rather than an official research collaborative project, designed to prepare the field for future CAM research. The work programme can be split into three broad tasks: the mapping of the current situation of CAM in the EU (by compiling existing information), developing a proposal for future CAM research (roadmap for future activities), and building a sustainable network of European CAM institutions relevant for research (coordination action). Dr Weidenhammer explained it was made up of a consortium of 16 beneficiaries from 12 different European countries, covering about three quarters of the European population. It also consisted of an advisory board consisting of many organisations for different CAM modalities.

Dr Weidenhammer referred the audience to his presentation slides again (see Annex 3) for an overview of the seven work programmes. He noted, however, that there was a lack of data for many, but did note that the results of Work Programme 6 show that there is more and higher quality research done in US and Asia than in Europe. He also noted that research needs to be more focused towards comparative effectiveness research, rather than focusing solely on randomised trials. The studies need to reflect daily practice rather than artificial studies carried out in controlled environments. In addition, Dr Weidenhammer mentioned that there is a need for funding research in the field, as there is little public funding national and EU-wide, aside from Horizon 2020.

Dr Weidenhammer finished his presentation by presenting a graph showing the gap between research and medical practice, examining the impact of research on family medical practice. A survey¹⁸ asked 100 General Practitioners (GPs) how important different aspects are for daily work. The most important aspect was own experience, less important is meta analyses – showing that evidence based medicine is perceived as more useful. Dr Weidenhammer concluded that there is a need to push CAM research into the field of public health, and political and scientific intent are needed. Ultimately, Dr Weidenhammer noted, nothing would be considered CAM, rather all possible contributions to help would be evaluated.

1.2.3. Questions & Answers

After the conclusion of Dr Weidenhammer's presentation, Mr Peterle shared an anecdote about how he had met a lady in Ljubljana who had to go to Austria to provide treatment to Slovenians. In Slovenia, a homeopathic practitioner by law needs a medical education, but, paradoxically, practicing homeopathy will result in losing medical licence. Mr Peterle stated that he could not understand that some patients have to travel long distances abroad, just for treatment that is provided ultimately by specialists of their home country.

He then opened the floor for questions, and the first came from his co-chair Ms Cabezón Ruiz. She stated that there are some misconceptions regarding conventional medicine, and she would not agree with the statement that conventional medicine focuses solely on the disease rather than the patient. She also noted that psychosomatic elements affect many illnesses, leading to treatments beyond conventional medicine. For example, high blood pressure can certainly be caused by stress, and cannot be cured simply by eating a low-salt diet.

¹⁸ Icezser & Linde, FoKom 2008

Ms Cabezón Ruiz asked if the speakers recognise that alternatives to conventional medicines should not be recommended for serious conditions. She presented two points, in one, a family in Italy refused antibiotics resulting in the death of a child, and the second, she noted that in 1970 in China, the average life expectancy was 43 years. When western medicine was introduced, this rose to 76 years. For these reasons, she cautioned against relying solely on alternative or complementary medicines.

Ms Cabezón Ruiz also spoke about the amount of research in the field. She noted that scientific methods exist to test the effectiveness of medicine, including studies which can be replicated, and it should therefore be there for CAM as well. Ms Cabezón Ruiz stated that there is a need for patient security, and knowledge of what is best of the patient.

Dr Nicolai took the floor first to respond to the comments. He stated that he fully agreed with Ms Cabezón Ruiz, that the focus should indeed be what is best for the patient. In the example Ms Cabezón Ruiz gave, it would be a case of malpractice, rather than a case of homeopathy gone badly. He noted that if a doctor is well trained, he will know when to give antibiotics, and when to prescribe CAM therapies. He took cancer as an example – in such cases, conventional medicine is imperative. However, CAM therapies can lessen the side effects of chemotherapy and can help with the psychological stress.

Dr Weidenhammer took the floor to add that there is a need for research on CAM – rather than blind advocacy. He stated that there is a need to know what kind of CAM works, and what kinds do not, and these studies must be carefully explored, especially with regard to the problem with placebo comparison. If a group of subjects who receive CAM treatments do better than a test group who receive conventional treatment, this must be recognised, even if it cannot be explained why it works. However, the topic is very complex, and thus further detail is beyond the scope of this workshop.

Dr Nicolai added that there is a wealth of information on the effectiveness of CAM widely available, for example, online, however, also within the field of conventional medicine there are many treatments which have not been proven by clinical evidence using a randomised clinical trial. For example, only about 10% of the guidelines of the US Clinical Heart Association is based on hard clinical evidence. Therefore, Dr Nicolai concluded, most evidence in both CAM and conventional medicine has to be based on clinical experience.

1.3. Part II: Traditional, complementary and alternative medicine: Policy and public health perspectives

1.3.1. The legal and policy framework of CAM in Europe

Ms Agnes MATHIEU-MENDES, European Commission, DG SANTE, Deputy Head of Unit, Medical products: quality, safety, innovation

Ms MATHIEU-MENDES started off her presentation by stating the definition of a 'medicinal product', as understood under EU law, which is a product presented to treat disease that is produced by industrial processes. A medicinal product has to comply with rules in order to ensure that it is safe, of good quality, and efficient for the patient. These rules were introduced not only to protect public health but also to ensure the free movement of goods within the EU.

Some time ago, the European Commission realised that they were not adapted to products including herbal medicines and homeopathic products. The rules proved to

be too burdensome and not suitable for the free circulation of products. It was then decided to adopt specific rules to ensure a regulatory framework for these products, as well as public health protection.

Directive 2004/24/EC was adopted in 2004 for traditional herbal medicinal products. Nowadays the Directive's rules are well known to economic operators. It introduced a completely different system from that applicable to traditional medicines, where clinical trials (i.e. tests on animal and humans) are the norm. For traditional herbal medicinal products, only a plausible level of evidence of their medicinal use throughout a period of at least 30 years, including 15 years in EU, is necessary. This does not prevent companies from using other routes of authorisation, such as the 'well-established use' system where a company submits a dossier containing bibliographical information, or the normal procedure for medicinal products.

Ms Mathieu-Mendes indicated that the regulatory framework for traditional herbal medicinal products is unique and complex, since certain products can be marketed either as food or pharmaceutical products. Products treating diseases should in principle fall under pharmaceutical legislation. Nevertheless, over the years a number of economic operators have used food supplement legislation to seek authorisations, since no indication of disease treatment is needed. Therefore, there is an alternative regulatory framework to the pharmaceutical legislation, and it is up to MS to classify products on a case by case basis, depending on their presentation and claimed effects.

When the Directive was introduced, companies showed a lack of interest in the simplified registration procedure. However, over the years, companies have understood the process and submitted applications. Since December 2015, more than 2629 applications have been received, and at least 1577 traditional use registrations were granted by MS. It can therefore be said today that the Directive works, although some MS are using the simplified framework more than others, due to the presence of food legislation. There is a notable difference in the implementation and uptake of the Directive between MS.

Ms Mathieu-Mendes then went on to talk about the work done within the EU on the subject. The European Medicines Agency (EMA) carries out scientific work on herbal medicines, while the Council of Europe establishes standards of quality. Meanwhile, the European Commission drafts decisions as regards the list of entry of herbal substances (i.e. for use in traditional herbal medicinal products). The list is currently limited to 10 herbal substances, such as *melaleuca alternifolia*. At the end of the day it is up to MS competent authorities to grant the marketing authorisations to herbal medicine producers.

A challenge experienced by the European Commission as regards the Directive is the fact that it has received complaints from economic operators in the past years as regards the Directive's complexity. Consequently, a REFIT platform consisting of government players and other stakeholders analysed the complaints and issued an Opinion on the submission by businesses on the Traditional Herbal Medicinal Products Directive on 7 June 2017. The question of whether the legislation should be changed, at the risk of compromising the protection of public health, is not being considered by the European Commission. It is currently waiting for the results of the REFIT evaluation of the regulation on health claims, since it is aware of companies' complaints as regards the impossibility to grant health claims for botanicals. Once it is published, it will be clearer whether the main problem lies with the Directive or the health claims. For the moment, the EC is of the opinion that legislation is relatively predictable for economic operators, and is focusing on making its implementation less burdensome.

Ms Mathieu-Mendes finished her presentation by briefly talking about the framework on homeopathic medicinal products (Directive 92/73/EC). The Directive introduced a simplified registration procedure only for homeopathic products administered orally or externally (i.e. not by injection), that have no specific indication on the labelling (i.e. cannot claim to treat diseases), and are enough diluted to guarantee the safety of the patient. Instead of demonstrating quality, safety and efficacy, as in the normal procedure for medicinal products, the quality of the homeopathic medicinal product is of importance here.

1.3.2. Integrating CAM into EU healthcare systems

Dr Stéphane ESPINOSA, World Health Organization (WHO), Consultant in the Traditional, Complementary and Integrative Medicine (TCI) Unit in the Department of Service Delivery and Safety (SDS)

Dr Stéphane ESPINOSA started his presentation by reading out a statement from the senior management of the World Health Organisation (WHO). The integration of traditional and complementary medicine into national health systems provides solutions for strengthening health systems in terms of service delivery, workforce, infrastructure, medical products and information exchange. An increasing number of patients want a more integrated approach to medical care, which is adapted to their individual needs and preferences. However, there exists a dichotomy in the medical world where professionals from the traditional and complementary medicine systems are not communicating. The WHO encourages further dialogue between them, in order to meet and better integrate the different approaches to healthcare. The inclusion of traditional and complementary medicine in the universal health coverage umbrella should be based on indicators with the same standards as for Western medicine. This covers workforce competency and good data on the safety, quality and effectiveness of traditional and complementary medical products and practices obtained, while applying the full range of evidence instruments from randomised controlled trials to qualitative research.

Dr Espinosa then gave a brief introduction on the importance of terminology, highlighting that at the WHO the focus lies on traditional and complementary medicine (T&CM). It is aware that a medical system perceived as traditional in one country may be seen as complementary in another. Furthermore, instead of alternative medicine, the WHO is focusing on integrative medicine. The reason is that with integrative medicine there is an emphasis on the benefits of various medical systems at the health system level, whereas with alternative medicine there is a situation of distant or separate approaches. Examples of the successful integration of various medical systems are China (service delivery) and India (workforce). In China there is a State administration regulating traditional Chinese medicine, which represents 18% of medical visits (900 million visits/year) and 16% of inpatients (13 million patients/year). In India, there is a Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH). There are over 780,000 registered AYUSH practitioners, and 1 million village-based AYUSH health practitioners.

In 2012 the WHO asked countries what the challenges are that they face with respect to regulatory issues in the field of traditional and complementary medicine. The majority of countries shared the same concerns. Dr Espinosa referred to the third slide in his presentation (available in Annex 3) when presenting the survey results. The main concern is a lack of research data. In second and third place respectively are concerns over the lack of appropriate mechanisms to control and regulate traditional

and complementary medicine advertising and claims, as well as herbal products. Taking this into account, and bearing in mind the importance played by traditional and complementary medicine in various aspects of health systems such as service delivery and workforce (fourth slide of presentation), the WHO consequently set out different areas of work that are currently being developed.

In 2014 the WHO Traditional Medicine Strategy 2014-2023 was published, which has two goals. The first is to make sure that the potential contribution of T&CM to health, wellness, people-centred health care and universal health coverage is harnessed. Secondly, the safe and effective use of T&CM through the regulation, research and integration of T&CM products, practices and practitioners into the health system should be promoted. As part of the Strategy, three strategic objectives are currently being worked on. The first is to build a knowledge base for the management of T&CM through policies. The second is to strengthen quality assurance, safety, proper use and effectiveness by regulation. Finally, the third one is to promote universal health coverage by integrating T&CM.

This comes within the context of the World Health Assembly (WHA) Resolution on Traditional Medicine (WHA67.18) adopted in May 2014. It urges MSs to adapt, adopt and implement the WHO strategy as a basis for national T&CM programmes and/or work plans. Furthermore, MS should develop and implement working plans to integrate traditional medicine into health services, particularly at the primary healthcare level, as well as report to the WHO on progress in implementing the strategy. In return, the Resolution requests the WHO Director General to facilitate MS implementation of the WHO strategy, as well as provide policy and technical guidance on how to integrate T&CM into healthcare systems, and help ensure the safety, quality and effectiveness of T&CM services. Of further relevance is the WHA Resolution on Strengthening Integrated, People-Centered Health Services (WHA69.24) adopted in May 2016. It urges WHO MS to integrate T&CM into modern health services, based on knowledge-based policies, while assuring the safety, quality and effectiveness of health services and taking into account a holistic approach to health.

The implementation of the WHO's T&CM work strategy has been rolled out into five articulated work areas. Dr Espinosa referred to the slides in the second half of his presentation when talking about these work areas. The first focuses on leadership, namely in helping MS integrate T&CM into their national health systems (i.e. developing best practices), while ensuring the quality and safety of T&CM services, and facilitating the networking of T&CM professionals and regulators. Secondly, the work area on research and knowledge aims to build a large database with an access platform on T&CM clinical evidence, as well as a T&CM knowledge platform. The WHO will also coordinate and support collaborative research projects enabling stakeholders from different WHO MS to share their experiences.

The third work area focuses on the normative aspect of regulating T&CM. This includes the developing of technical documents, including guidelines on the quality and safety of herbal medicines. Furthermore, as part of its work on improving the international terminology and classification of T&CM, a Chapter on traditional medicine has been added to the international classification of diseases (currently being revised by the WHO). This further enables the use of traditional medicine in an integrative medicine context. Benchmarks for T&CM practices such as acupuncture and Ayurveda have also been developed under this third work area. Under its fourth work area, concerning the building of institutional capacity, the WHO has run a series of interregional training workshops for the capacity-building of government officials, as well as formulated capacity-building tools (i.e. benchmarks for training in T&CM practices). Lastly, under

its fifth work area focusing on evidence-based policy and monitoring and assessing, the WHO supports countries to implement the WHO strategy on T&CM, as well as monitors their progress, and conducts global surveys for the building of a database to be used as a repository for WHO MS experiences.

Dr Espinosa concluded his presentation with a key message, which is that both the patients and wider public will benefit from the integration of Western medicine and T&CM into health systems, bearing in mind that quality, safety and effectiveness are ensured.

1.3.3. Questions & Answers

Mr Peterle opened the floor for discussion.

Mr Madan THANGAVELU (European Ayurveda Association) remarked the importance of keeping the debate alive on the need for CAM therapies. Leadership is needed in order to re-examine the current legislation in order to prioritise the medical practices that are most beneficial to our society. He cited the example of the UK, which spends 22 million pounds on a daily basis in order to tackle type 2 diabetes, a preventable condition in 70-80% of cases. He further highlighted that experts should be consulted by policymakers, and they should first and foremost bear in mind the patients' need for CAM therapies when debating new legislation.

Ms Cabezón Ruiz highlighted the importance of research, using rigorous scientific methodologies, in order to prove the safety and quality of CAM therapies. There is irrefutable proof that conventional medicine has improved living standards and survival rates. In light of this, CAM therapies could never be presented as an alternative, but rather as complementary options, since they cannot substitute for conventional medicine.

Mr Peterle then asked Dr Espinosa and Ms Mathieu-Mendes how the EU and WHO can further collaborate in their work on CAM. He also asked Ms Mathieu-Mendes whether the European Commission is doing anything else to facilitate the integration of CAM into MS healthcare systems.

Dr Espinosa first reacted to the comments made by Mr Thangavelu and Ms Cabezón Ruiz. He emphasised the fact that the importance of T&CM varies according to the country, namely whether it is a developing country and if it offers universal health coverage. However, the integration of T&CM improves health systems in all countries by making them more affordable and sustainable. As regards Mr Peterle's question, Dr Espinosa answered that the WHO would like to have more collaboration with the EU and its MS on this topic. It has had contact with European officials on a national level, and would find it interesting to speak at a group level with European countries.

Ms Mathieu-Mendes answered Mr Peterle's questions by stating that in the interest of maintaining public health, the European Commission remains dedicated to ensuring high standards of quality, safety and efficacy in its work concerning herbal medicines. As long as a product fulfils these criteria, it can be used within European health systems. She noted that the distinction between traditional and complementary substances is blurred, since a number of herbal chemicals are currently being used in medicines in light of their disease-fighting properties.

1.3.4. Closing remarks by the Chair

Mr Peterle thanked the speakers for their contributions and for sharing their knowledge on the topic. He remarked that both the Western and CAM medicine systems are part

of what he describes as 'medicinal pluralism', implying that in democratic societies choice is preferred over monopolies. This choice should be made available to the patients that need it, while respecting certain criteria and principles (i.e. safety). MS should overcome their differences and share good practices, with the help of the European Commission. He mentioned the example of the Italian region of Tuscany, where the integrative medicine model has been introduced, as a good practice. The majority of hospitals there offer conventional and CAM therapies, with doctors referring patients to both. Mr Peterle concluded by stating that efficacy and patient-centeredness are two elements that should be prioritised in the future, in order to accelerate the progress in MS uptake of CAM therapies.

ANNEX 1: PROGRAMME

Complementary and alternative therapies for patients today and tomorrow

Monday 16 October 2017 from 16.00 to 18.00
European Parliament, Brussels

AGENDA

Co-Chairs:

Mr Alojz PETERLE (MEP), Ms Soledad CABEZÓN RUIZ (MEP)

16:00 – 16:10 Opening and welcome by the chair

Part 1 – The current state of play of complementary and alternative therapies (CAM) in Europe

16:10 – 16:25 **Overview of CAM therapies in Europe**
Dr Ton NICOLAI, EUROCAM Spokesperson

16:25 – 16:40 **The status of research on CAM across the EU**
Dr Wolfgang WEIDENHAMMER, Coordinator of the CAMBRELLA
project

16:40 – 17:00 **Questions & Answers**

Part 2 – Traditional, complementary and alternative medicine: policy and public health perspectives

17:00 – 17:15 **The legal and policy framework of CAM in Europe**
Ms Agnes MATHIEU-MENDES, European Commission, DG SANTE,
Deputy Head of Unit, Medical products: quality, safety, innovation

17:15 – 17:30 **Integrating CAM into EU healthcare systems**
Dr Stéphane ESPINOSA, World Health Organization (WHO),
Consultant in the Traditional, Complementary and Integrative
Medicine (TCI) Unit in the Department of Service Delivery and
Safety (SDS)

17:30 – 17:50 **Questions & Answers**

17:50 – 18:00 **Closing remarks by co-chairs**

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Dr Ton Nicolai, EUROCAM Spokesperson

Ton Nicolai studied medicine at the Leiden University and graduated as a medical doctor in 1972. He started working as a General Practitioner and continued working as such for eleven years. Astounded by the fact that so many patients could not be cured and were supposed to take long-term or even life-long medication as mere palliatives, he started to look for other therapeutic options. He studied several therapies in the field of Complementary and Alternative Medicine, including homeopathy, acupuncture, manual therapy and naturopathy. He eventually decided to focus on homeopathy and from 1988 to 2017 he has been working as a consultant homeopathic doctor.

He served on the Board of the Netherlands Homeopathic Medical Association (VHAN) and the International Homeopathic Medical League (LMHI). He was one of the founders of the European Committee for Homeopathy (ECH) in 1990, served as its political coordinator and secretary, and later on as its president from 2000-2012. Over the last few years he has been working as spokesperson of EUROCAM, the foundation representing patients and trained health professionals (medical doctors, veterinarians and other practitioners) in the sector of Complementary and Alternative Medicine across Europe.

He is author of several reports, position papers and articles. He received several awards for his international work: he has become Companion of the Order of Orange-Nassau on behalf of the Queen of the Netherlands, Honorary Member of the International Homeopathic Medical League (LMHI), Honorary Fellow of the Faculty of Homeopathy in the United Kingdom, and he received the Globular Politics Award from the German Homeopathic Medical Association DZVhÄ.

Dr Wolfgang Weidenhammer, The status of research on CAM across the EU

Wolfgang Weidenhammer, born in 1952 and trained as a psychologist, PhD in Human Biology (Medical Faculty, University Munich) and Philosophy (Dept. Psychology, University Koblenz-Landau).

Holding various positions as research assistant since 1979 he worked as an academic researcher at Division of Medical Psychology, Psychiatric University hospital Erlangen from 1986 to 1990. He was Chief bio-statistician at Institut für Klinische Forschung, Hamburg-München (CRO) from 1990 to 1994. From 1994 until 2017 he worked as an academic researcher at the Competence Centre for Complementary Medicine and Naturopathy (leader: Prof Dr D Melchart), University hospital 'Klinikum rechts der Isar', TU Munich.

He has been the project coordinator of EU-FP7 project CAMbrella from 2010 to 2012, member of various scientific societies, of the Scientific Advisory Board of TCM Hospital Bad Kötzing, of the Scientific Board of EICCAM (European Information Centre on CAM) and founding member of the European chapter within ISCMR (International Society for Complementary Medicine Research). Since 1980 he has published approx. 160 scientific papers and articles.

Ms Agnes Mathieu-Mendes, European Commission, DG SANTE, Deputy Head of Unit, Medical products: quality, safety, innovation

Agnès Mathieu-Mendes is Deputy Head of the unit dealing with the quality, safety and innovation of medicinal products in the Directorate General on Health and Food Safety in the European Commission. Her responsibilities include the implementation of the Falsified Medicines Directive, the Clinical Trials Regulation, good manufacturing practices, good distribution practices and mutual recognition agreements on GMP with third countries. She has been working for many years in the pharmaceutical field such as the authorisation process of medicinal products or the orphan medicinal products.

Agnès Mathieu-Mendes joined the European Commission in 2006 to work on the Better Regulation agenda of the Directorate General for enterprise and industry.

She is a pharmacist by training and has a diploma in pharmaceutical engineering and industrial technology. Prior to the European Commission, Agnès Mathieu-Mendes held a position in the pharmaceutical industry and in the Council of Europe.

Dr Stéphane Espinosa, World Health Organization (WHO), Consultant in the Traditional, Complementary and Integrative Medicine (TCI) Unit in the Department of Service Delivery and Safety (SDS)

Dr Stéphane Espinosa is a consultant in the Traditional, Complementary and Integrative Medicine (TCI) Unit, Department of Service Delivery and Safety (SDS), World Health Organization (WHO).

He is currently involved in the implementation of the “WHO Traditional Medicine Strategy 2014-2023,” working in the area of knowledge building with the development of a traditional and complementary medicine knowledge platform and international terminology. In the field of standards and norms, since 2014 he has participated in the revision process of the International Classification of Diseases for Mortality and Morbidity Statistics, 11th Revision (ICD-11 MMS), with emphasis on quality assurance and the chapter on traditional medicine.

Dr Stéphane Espinosa has an extensive and varied background with diplomas ranging from physics to engineering and healthcare, specializing in traditional and complementary medicine. He is a licensed acupuncturist. His professional experience spans from Asia to Europe and South America. Prior to WHO, Dr Espinosa worked in private, multidisciplinary clinics.

ANNEX 3: PRESENTATIONS

Presentation by Ton Nicolai



Overview of CAM therapies in Europe

Workshop

“Complementary and alternative therapies for patients today and tomorrow”,
European Parliament, 16 October 2017
by Dr Ton Nicolai, EUROCAM spokesperson

EUROCAM 2

EUROCAM

- ❖ EUROCAM is a foundation uniting European organisations representing CAM patients and trained CAM health professionals, (medical doctors, veterinarians and other practitioners)
- ❖ Aim: promoting the contribution of CAM - Complementary and Alternative Medicine - to better health in Europe.
- ❖ Objectives:
 - promoting and facilitating CAM's role in maintaining citizens' health
 - highlighting the health promotion and illness prevention aspects of CAM for EU public health policy and programmes,
 - advancing the accessibility, affordability and availability of CAM

Citizens' demand for CAM

- ❖ CAM is a societal phenomenon in the whole Western world; strong increase over the last 2 decades
- ❖ Increasing personal responsibility for one's own health
- ❖ Preference of a more holistic view of health and healing that goes beyond managing symptoms
- ❖ Preference of more gentle and natural therapies first, before more potent or synthetic ones
- ❖ Dissatisfaction with conventional medicine, i.e. unpleasant side effects, ineffective treatment, long-term – or even lifelong – drug regimens.

CAM – its use in Europe

❖ *12-month prevalence in general population:*

- 9.8 – 76.0% use any CAM
- 1.8 – 48.7% visit CAM doctors/practitioners
- 8.0 – 27.3% use OTC

[Ref: Harris PE et al (2012). Int J Clin Pract, 66:924-939]

❖ *12-month prevalence in patients with chronic diseases:*

up to 90% of people with chronic conditions, such as arthritis, asthma, migraine, etc., more than 50% of all breast cancer patients

- ❖ Majority of EU citizens would like conventional MDs to be more supportive of and more knowledgeable about CAM, and have a greater role in terms of referral to CAM and as sources of information.

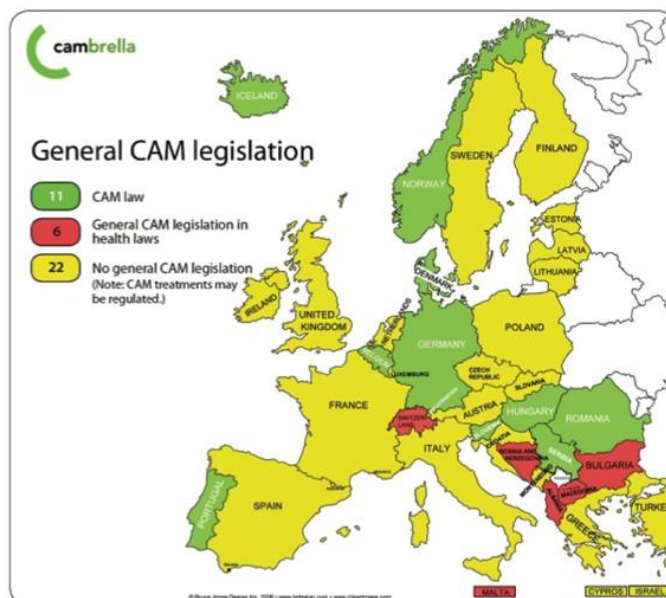
[Ref: CAMbrella report]

CAM – its use in Europe

- ❖ 150,000 MDs with additional CAM qualification
- ❖ > 180,000 CAM practitioners without a full medical education
- ❖ Mostly provided by MDs:
 - acupuncture 80,000 MDs (also 16,000 practitioners)
 - homeopathy 45,000 MDs (also 4,500 practitioners)
 - naturopathy 15,000 MDs
 - anthroposophic medicine 4,500 MDs
 - neural therapy 1,500 MDs
- ❖ Mostly provided by CAM practitioners without a full medical education:
 - herbalism, manual therapies (osteopathy, chiropractic), reflexology, shiatsu, yoga, tai chi & qigong.

[Ref: CAMbrella report]

Statutory regulation of CAM



Statutory regulation of CAM

- ❖ 17 of 39 European countries have a general CAM legislation
 - 11 of these have a specific CAM law
 - 6 countries have sections on CAM included in their health laws
- ❖ Some countries have regulations on specific CAM therapies.

CAM therapy	# of European countries
Acupuncture	26
Anthroposophic medicine	7
Ayurveda	5
Chiropractic	26
Herbal medicine/phytotherapy	10
Homeopathy	24
Massage	20
Naturopathy	8
Neural therapy	3
Osteopathy	15
Traditional Chinese medicine	10

[Ref: CAMbrella reports]

Starting integration of CAM in Europe?

- ❖ Increasing numbers of patients integrating conventional medicine and CAM
- ❖ 150,000 MDs and over 180,000 other CAM health professionals
- ❖ Increasing numbers of GPs referring to CAM professionals
- ❖ Increasing numbers of hospitals providing integrated healthcare (conventional and CAM), mostly out-patients, also in-patients
- ❖ Professorial CAM chairs in France, Germany, Hungary, Italy, Norway, Sweden, Switzerland and United Kingdom
- ❖ CAM familiarisation courses in undergraduate medical curricula at 30-40% of European universities

CAM therapies in Europe

- ❖ Acupuncture
- ❖ Anthroposophic medicine
- ❖ Ayurveda
- ❖ Herbal medicine / Phytotherapy
- ❖ Homeopathy
- ❖ Naturopathic medicine
- ❖ Osteopathy
- ❖ Traditional Chinese Medicine (TCM)
- ❖ and more

Do these therapies have anything in common?

Examples from actual practice

1. Patient seriously ill, affected by highly virulent bacteria
Antibiotics are life saving.

2. Patient having recurrent infections, many courses of
antibiotics. No adequate solution. Also leading to antimicrobial
resistance.

It's about **susceptibility**

CAM can diminish susceptibility, enhance the patient's level of
health and resilience. No (or rare) further infections.

Examples from actual practice

1. Patient with asthma or migraine or hypertension, etc.
Conventional treatment: management of symptoms by long--term use of conventional medication. No final, effective solution.

2. Same patient with asthma or migraine or hypertension, etc.
CAM doctor/practitioner: what made this patient susceptible?

It's about **susceptibility**

CAM can diminish susceptibility, enhance the patient's level of health and resilience. Less or even no conventional medication at all required.

Different models of healthcare

- ❖ Western medicine is based on a specific – biomedical – model which is so deeply interwoven within our society and healthcare system that it may be forgotten that it is but one way of thinking; one of many perspectives.
- ❖ A comparison of Western medicine and Complementary and Alternative Medicine (CAM) could give a misleading impression that there are just differences in the technology and instruments used.
- ❖ The essential difference however lies in the underlying paradigms, the basic concepts of and philosophical perspectives on health and disease/illness.

Western biomedical model

- ❖ Mind and body are separated; body as an object, a complex machine.
 - ❖ Illness results from biochemical or localised tissue disruption or specific pathogen; disease is a mechanical fault, an abnormal entity in the body.
 - ❖ Treatment: combating disease by repairing, neutralising, or intervening in pathological process with the aid of chemical substances (prescription drugs) or surgery.
 - ❖ Treatment as much standardised as possible (treatment protocols and guidelines).
 - ❖ Physician primarily responsible, patient as a passive recipient of treatment.
-

Successes of the biomedical model

- ❖ Trauma medicine, intensive care
 - ❖ Antisepsis
 - ❖ Blood transfusions
 - ❖ Surgery
 - ❖ Transplantations
 - ❖ Treatment of life-threatening diseases (antibiotics, cortisone, chemotherapy)
 - ❖ Treatment of serious psychiatric conditions (psychotropic prescription drugs)
 - ❖ Vaccination
-

Limits to the biomedical model

- ❖ Biomedicine usually manages symptoms of chronic diseases and does not restore patients to health and autonomy.
- ❖ EMA: 197,000 European citizens die annually from the effects of conventional prescription drugs, leading to a total cost to society in the EU of €79 billion.
- ❖ Use of prescription drugs often lead to long-term dependency including risk of 'adverse' effects.
- ❖ Because in biomedicine every medical condition is seen as a separate pathology and needs to be addressed accordingly, there is a great risk of polypharmacy, i.e. the use of multiple medications, especially in the elderly.
- ❖ Polypharmacy is associated with a decline in physical and instrumental activities of daily living, with negative consequences, such as increased risk of morbidity and mortality. In addition, it increases medical costs.

CAM model

- ❖ Human beings as adaptable, self-regulating, creative biological systems.
- ❖ Illness/disease is a disturbed life process with causes at physical, emotional, social, mental, spiritual levels.
- ❖ Patients themselves take responsibility for mental and physical health.
- ❖ Treatment: mobilising and stimulating self-regulating capacity, restoring the balance in the psychosomatic system with the eventual aim: creating and maintaining the health and wellbeing and reinforcing the autonomy and resilience of the patient.
- ❖ Care is individualised; responsibility shared between physician and patient.

Benefits of CAM

- ❖ Supporting and inducing the self-regenerating process of the person; if recovery can occur from this, the need for later high-impact, high-cost interventions is reduced.
- ❖ Safe treatment with hardly any adverse effects; no morbidity or mortality as from conventional prescription drugs.
- ❖ Reduced need of conventional prescription drugs and long-term dependency on them.
- ❖ Reduced need of antibiotics, thus helping to reduce the problem of antimicrobial resistance.
- ❖ High patient satisfaction, increased quality of life, and reduction of absenteeism.
- ❖ Mostly low-cost treatment.

Limits to CAM

- ❖ Protection of life itself always has the highest priority, so in serious, life-threatening diseases (sepsis, cancer, etc.), CAM therapies are relegated to a secondary, additional role.
- ❖ If technical solutions are required, e.g. operations because of disabling anatomical abnormalities, CAM therapies have no role to play.
- ❖ In a number of EU Member States CAM practices and medicinal products are unregulated and may pose risks to the health and safety of patients. CAM professions should therefore be regulated, based on clearly defined qualifications and competences. CAM medicinal products should comply with quality and safety standards.

Collaboration of both models

- ❖ A collaborative approach is making headway in the USA and has started in Europe. The **Academic Consortium for Integrative Medicine & Health** in the USA 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.
- ❖ The Consortium now includes over 70 highly esteemed academic medical centres in the USA, including Harvard Medical School, Yale University, Stanford University, Mayo Clinic, Johns Hopkins University, etc.
- ❖ According to the Consortium every individual has the right to healthcare that:
 - Provides dignity and respect
 - Includes a caring therapeutic relationship
 - Honours the whole person - mind, body, and spirit
 - Recognizes the innate capacity to heal
 - Offers choices for complementary and conventional therapies.

Concluding statement



Dr Margaret Chan,
WHO Director-General
2006–2017,
in Beijing, 2008.

The two systems of traditional and Western medicine need not clash. Within the context of primary health care they can blend together in a beneficial harmony, using the best features of each system and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made....The time has never been better, and the reasons never greater, for giving traditional medicine its proper place in addressing the many ills that face all our modern – and our traditional – societies.

Presentation by Wolfgang Weidenhammer



Klinikum rechts der Isar
Competence Center for
Complementary Medicine and
Naturopathy
Technische Universität
München, Germany

The status of research on CAM across the EU



Wolfgang Weidenhammer

EP-Workshop "Complementary
and alternative therapies for
patients today and tomorrow"
Brussels, October 16, 2017



The status of research on CAM across the EU



Starting point

The status of CAM research in terms of quantity and quality

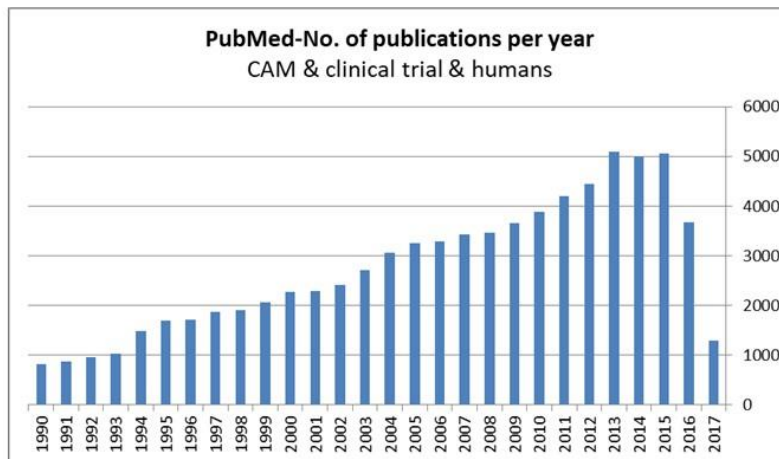
- Has been poor in the beginnings
- Has become much better in the past 25 years
- But still needs improvement in many ways



The status of research on CAM across the EU



Quantity of publications on clinical trials in CAM since 1990 (pubmed listed*)



*retrieved Sept 25,2017



The status of research on CAM across the EU



Some issues when giving an outline of the status of CAM research

- Difficult to identify researchers / subject of research as European
- ‚CAM‘ means a number of different modalities used for a wide variety of medical conditions
- Complex interventions (interacting effects)
- Different targets (feasibility, effectiveness, safety, cost-effectiveness, efficacy, mechanism of action)
- Chronic and/or functional diseases (long-term treatment)
- Model validity (e.g. qualification of the therapist)
- Appropriate choice of control groups
- Often ‚soft‘ outcomes
- Patient plays an active role in treatment (see also patient-physician relationship)
- Traditional use („reversed pharmacology“)



The status of research on CAM across the EU



Example: Acupuncture

A comprehensive overview on evidence regarding effectiveness, safety and costs of acupuncture from 2017*

A total of 136 systematic reviews, including 27 Cochrane systematic reviews were included in this review, along with 3 network meta-analyses, 9 reviews of reviews and 20 other reviews.

The review covers 122 different medical conditions.

Meta-analyses were conducted for 62 of the non-Cochrane systematic reviews. This review includes pooled data from more than 1,000 randomised controlled trials.

*McDonald J, Janz S. The Acupuncture Evidence Project: A Comparative Literature Review (Revised edition). Brisbane: Australian Acupuncture and Chinese Medicine Association Ltd; 2017. <http://www.acupuncture.org.au>.



The status of research on CAM across the EU



Example: Acupuncture

A comprehensive overview on evidence regarding effectiveness, safety and costs of acupuncture from 2017

Evidence Level	Number of Conditions
Strong Evidence of effect	8
Moderate Evidence effect	38
Unclear/mixed evidence	71
Little of no evidence of effect	5
Total conditions with some evidence of effect (any level)	117
Total conditions reviewed	122



The status of research on CAM across the EU



Example: Acupuncture

A comprehensive overview on evidence regarding effectiveness, safety and costs of acupuncture from 2017

Table 1. Conditions with strong evidence supporting the effectiveness of acupuncture	
Reviews with consistent statistically significant positive effects and where authors have recommended the intervention. The quality of evidence is rated as moderate or high quality.	
<ul style="list-style-type: none"> - Allergic rhinitis (perennial & seasonal) - Chemotherapy-induced nausea and vomiting (with anti-emetics) - Chronic low back pain - Headache (tension-type and chronic) 	<ul style="list-style-type: none"> - Knee osteoarthritis - Migraine prophylaxis - Postoperative nausea & vomiting - Postoperative pain



The status of research on CAM across the EU



A comprehensive overview on evidence regarding effectiveness, safety and costs of acupuncture from 2017

Table 2. Conditions with moderate evidence supporting the effectiveness of acupuncture	
Reviews reporting all individual RCTs or pooled effects across RCTs as positive, but the reviewers deeming the evidence insufficient to draw firm conclusions. The quality of evidence is rated as moderate or high quality.	
<ul style="list-style-type: none"> - Acute low back pain - Acute stroke - Ambulatory anaesthesia - Anxiety - Aromatase-inhibitor-induced arthralgia - Asthma in adults - Back or pelvic pain during pregnancy - Cancer pain - Cancer-related fatigue - Constipation - Craniotomy anaesthesia - Depression (with antidepressants) - Dry eye - Hypertension (with medication) - Insomnia - Irritable bowel syndrome - Labour pain - Lateral elbow pain - Menopausal hot flushes 	<ul style="list-style-type: none"> - Modulating sensory perception thresholds - Neck pain - Obesity - Perimenopausal & postmenopausal insomnia - Plantar heel pain - Post-stroke insomnia - Post-stroke shoulder pain - Post-stroke spasticity - Post-traumatic stress disorder - Prostatitis pain/chronic pelvic pain syndrome - Recovery after colorectal cancer resection - Restless leg syndrome - Schizophrenia (with antipsychotics) - Sciatica - Shoulder impingement syndrome (early stage) (with exercise) - Shoulder pain - Smoking cessation (up to 3 months) - Stroke rehabilitation - Temporomandibular pain



The status of research on CAM across the EU



Example: Acupuncture

A comprehensive overview on evidence regarding effectiveness, safety and costs of acupuncture from 2017

Table 4. Conditions with little or no evidence supporting the effectiveness of acupuncture	
Reviews have consistently found little support for acupuncture. The quality of the evidence is consistently low or very low. Further research required.	
- Alcohol dependence	- Nausea in pregnancy
- Cocaine addiction	- Smoking cessation (more than 6 months)
- Epilepsy	



The status of research on CAM across the EU



Example: Homeopathy

Clinical trials overview

By the end of 2014, 189 randomised controlled trials of homeopathy on 100 different medical conditions had been published in peer-reviewed journals:*)

Of these, 104 papers were placebo-controlled and were eligible for detailed review:

- 41% were positive (43 trials) – finding that homeopathy was effective
- 5% were negative (5 trials) – finding that homeopathy was ineffective
- 54% were inconclusive (56 trials)

*) <http://facultyofhomeopathy.org/research/>



The status of research on CAM across the EU



CAMbrella – in a nutshell



Aims	to review the status quo of CAM from different perspectives in the EU and to provide a proposal for a CAM research roadmap
Impact	Research roadmap and network to enable sustainable and prioritised CAM research in the EU
Consortium	16 participants from 12 European countries plus one adjunct partner from Netherlands
Funding	max 1.5 m. € (FP7/2007-2013, GA No. 241951) Coordination action
Coordinator	Klinikum rechts der Isar, Techn. Univ. Munich, Competence Centre for Complement Med & Naturopathy; W Weidenhammer
Time frame	Jan 1, 2010 – Dec 31, 2012
Information	www.cambrella.eu ; Weidenhammer et al. Forsch Komplmed 2011;18:69-76; Walach and Weidenhammer (eds.), Forsch Komplmed 2012;19 (suppl 2).



The status of research on CAM across the EU



CAMbrella – the task

from the Work programme of Call FP7-Health 2009



„In order to create the knowledge base concerning the **demands** for Complementary and Alternative Medicine (CAM) and the **prevalence of its use in Europe**, consensus on the **terminology of CAM** and the definition of respective CAM methods needs to be established.

The current state with respect to the **provider's perspective** as well as **needs and demands of the citizens** should be explored; the different **legal status** of CAM in EU Member States needs to be taken into account.

A **roadmap for future European research** in this area should be developed“.

*...complemented by the **Global perspective***



The status of research on CAM across the EU



Summarized:



- i) Mapping of the current situation of CAM in the EU
→ **Compiling existing information**
- ii) Developing a proposal for future CAM research
→ **Roadmap for future activities**
- iii) Building a sustainable network of European CAM institutions relevant for research
→ **Coordination action**



The status of research on CAM across the EU



Advisory Board
EPHA - European Public Health Association
ECCH - European Central Council of Homeopaths
EFCAM - European Forum for Complementary and Alternative Medicine
ECHAMP - European Coalition on Homeopathic and Anthroposophic Med. Products
ANME - Association of Natural Medicine in Europe
EICCAM - European Information Centre for Complementary and Alternative Medicine
ICMART - International Council of Medical Acupuncture and Related Techniques
ECH - European Committee for Homeopathy
EHTPA - European Herbal & Traditional Medicine Practitioners' Association
IVAA - International Federation of Anthroposophic Medical Associations
KB - Kneipp-Bund eV
ECPM - European council of doctors for plurality in medicine





The status of research on CAM across the EU



WP1: Terminology and Definitions of CAM Methods

Proposal for a pragmatic definition of CAM as a working document.



WP2: Legal status and regulations of CAM in Europe

Review of legal and regulatory status of CAM in the European Union plus 12 associated states disclosed marked heterogeneity.

WP3: Needs and Attitudes regarding CAM among EU Citizens

Citizens' core attitudes and needs regarding CAM cover 'the whole person', safety, impartial, reliable and trustworthy information, wider access to and choice of CAM as well as clear regulatory and educational frameworks.

WP4: CAM use – the patients' perspectives

Data available from less than ½ EU States, poor data quality, huge range in prevalence rates, need for coherent, comprehensive and rigorous prospective data collection.

WP5: CAM use – the provider's perspective

CAM provision in EU comprises health care practitioners and physicians with different healing attitudes, medical background, training, certification, and practise. Scientific data are rare, need public registries.

WP6: The global perspective

European public investment in CAM stands in contrast to the large investments found in Australia, Asia and North America. More support is needed for a broader research repertoire, including qualitative and comparative effectiveness research.



The status of research on CAM across the EU



WP7: Roadmap for European CAM research



Methods

- literature review on CAM research methods
- Consideration of findings and conclusions from Work Packages 1-6
- expert workshop on CAM methods
- consensus meeting

Fischer FH et al. Key Issues in Clinical and Epidemiological Research in Complementary and Alternative Medicine – a Systematic Literature Review. *Forsch Komplementmed* 2012;19(suppl 2):51–60

Fischer FH et al. A Research Roadmap for Complementary and Alternative Medicine – What We Need to Know by 2020. *Forsch Komplementmed* 2014;21:e1–e16.

Fischer FH et al. High prevalence but limited evidence in complementary and alternative medicine: guidelines for future research. *BMC CAM* 2014, **14**:46.



The status of research on CAM across the EU



CAM research areas

- Key Area 1: CAM prevalence in the EU
- Key Area 2: Needs and attitudes of citizens, patients and providers
- Key Area 3: CAM safety
- Key Area 4: Comparative Effectiveness Research
- Key Area 5: Meaning / Context Factors in CAM
- Key Area 6: Models in CAM integration into health systems



Methodological considerations

- General research framework (e.g. mixed methods approach)
- Quantitative research methods / qualitative research
- Stakeholder involvement (especially patients)
- Selection of prioritized CAM modalities

Research infrastructure / networking / funding

- build sufficient research networks in Europe
- European CAM research coordination office to foster systematic communication between EU governments and researchers / stakeholders
- More public funding nationally and EU-wide

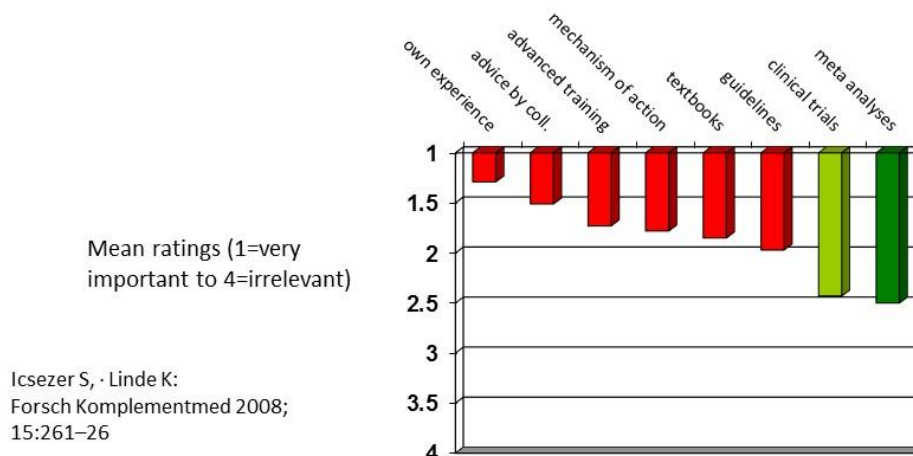


The status of research on CAM across the EU



Gap between research and medical practice

How important is ... for your practical work? Results from a survey among physicians (n=436) attending continuing medical education events





The status of research on CAM across the EU



Evidence based medicine: what it is and what it isn't*

"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means **integrating individual clinical expertise** with the **best available external clinical evidence from systematic research**."

" ... Evidence based medicine is not "cookbook" medicine. Because it requires a bottom up approach that integrates the **best external evidence with individual clinical expertise and patients' choice**, it cannot result in slavish, cookbook approaches to individual patient care."

*Sackett DL et al. BMJ 1996;312(7023):71-72.



The status of research on CAM across the EU



Final comment

"Such a strategy is required if complementary and traditional medicine is to shift from the marginal status it holds in most countries to having a significant role in national health care.

Political intent as well as **scientific** intent are needed to support such an agenda.

Ultimately, nothing would be considered complementary or alternative, orthodox or conventional. Rather, **all possible** contributions to health would be **evaluated for their promise and harnessed for the good of the public's health**".

Bodeker G, Kronenberg F. A Public Health Agenda for Traditional, Complementary, and Alternative Medicine. American Journal of Public Health 2002;92(10):1582-91

Presentation by Agnes Mathieu-Mendes



Complementary and alternative therapies for patients today and tomorrow

The legal and policy framework of CAM in Europe

Workshop at the European Parliament
16 October 2017- European Parliament, Brussels

Agnes Mathieu-Mendes

European Commission

Deputy Head of Unit

Directorate General for Health and Food Safety

Sante B4: Medical products: quality, safety, innovation

Disclaimer : This presentation only reflects the views of its author and does not necessarily reflect the opinion of the Commission

Health and
Food Safety



Background

- *Products used in complementary and alternative medicine, if they are medicinal products as defined in Community law, must comply with the strict requirements regarding quality, safety and efficacy laid down in that law.*
- *Medicines have to fulfil strict requirements regarding quality, safety and efficacy laid down in Community law*

Health and
Food Safety



Background

- *In order to enable certain of these products to be placed on the market, the Community adopted two directives regarding **homeopathic** (Directive 92/73/EC of the Council) and **traditional herbal medicinal products** (Directive 2004/24/EC of the Parliament and the Council) introducing a simplified registration procedure whilst maintaining an adequate level of protection of public health and safety*

Health and
Food Safety



Traditional herbal medicinal products

- *Traditional Herbal Medicinal products Directive 2004/24/EC*
- *No particulars and documents on tests and trials on safety and efficacy*
- *Plausible level of evidence of the medicinal use throughout a period of at least 30 years including 15 years in the Union*
- *Other routes of autorisation: well-established use or normal procedure for medicinal products*

Health and
Food Safety



State of play

- *Products can be marketed either as food or as pharmaceutical products*
- *Member States responsibility to classify on a case by case basis depending of the presentation and claimed effect*

Health and
Food Safety



State of play

- *Between Dec 15 and today, 2629 applications have been received*
- *at least 1577 traditional use registrations granted*

Health and
Food Safety



State of play

- *Commission Decision 2008/911/EC of 21 November 2008* establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products.
- *Examples: Melaleuca alternifolia, ... ongoing adoption for Sideritis herba and Valerianae radix*
- *After a scientific assessment by EMA*

Health and
Food Safety



Challenge

- *REFIT Platform Opinion on the submission by businesses on the Traditional Herbal Medicinal Products Directive: adoption: 07/06/2017*
- *Divergence in implementation and difference in uptake of THMP across Europe, possible simplification*
- *Conclusion: waiting the results of the Refit evaluation of the Regulation on health claims prior to taking any decision on the herbal legislation*

Health and
Food Safety



Homeopathics medicinal products

- *simplified registration procedure applies to homeopathic medicinal products that are administered orally or externally, that have no specific indication on the labelling and that are sufficiently diluted to guarantee the safety of the product*
- *main focus for the application for registration is the quality of the homeopathic medicinal product*

Health and
Food Safety



Thank you for your attention

Health and
Food Safety

Presentation by Stéphane Espinosa



Integrating CAM into EU healthcare systems

Workshop
"Complementary and alternative therapies for patients today and tomorrow"
European Parliament

16 October 2017

Dr Stéphane Espinosa | Consultant | Traditional, Complementary and Integrative Medicine Unit, Department of Service Delivery and Safety



Terminology

Traditional, Complementary, Alternative, Integrative

Country Examples in other regions:

China - traditional Chinese medicine (TCM)

18% of all medical visits are to TCM (> 900 million visits per year)

16% of all inpatients (> 13 million per year)

Top five diseases for admission to TCM hospitals:

Cerebrovascular accident, intervertebral disc displacement, haemorrhoids, ischaemic heart disease and essential hypertension

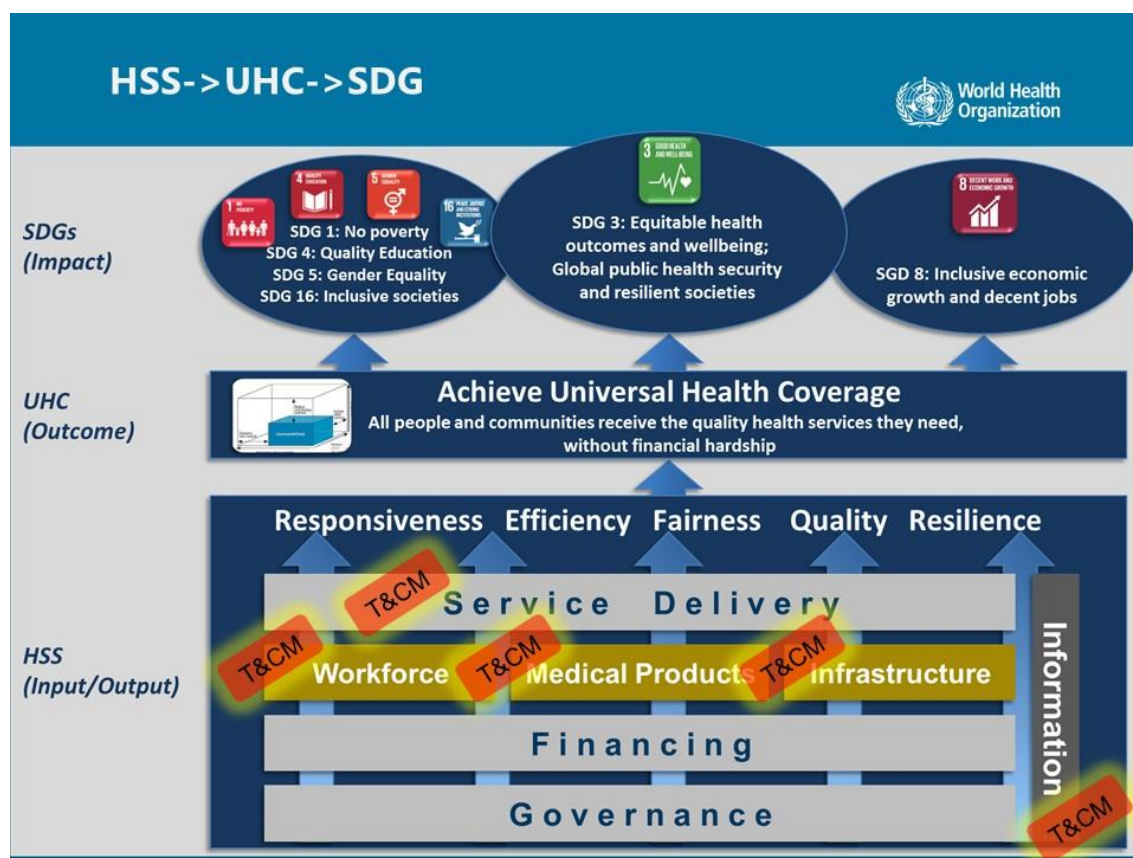
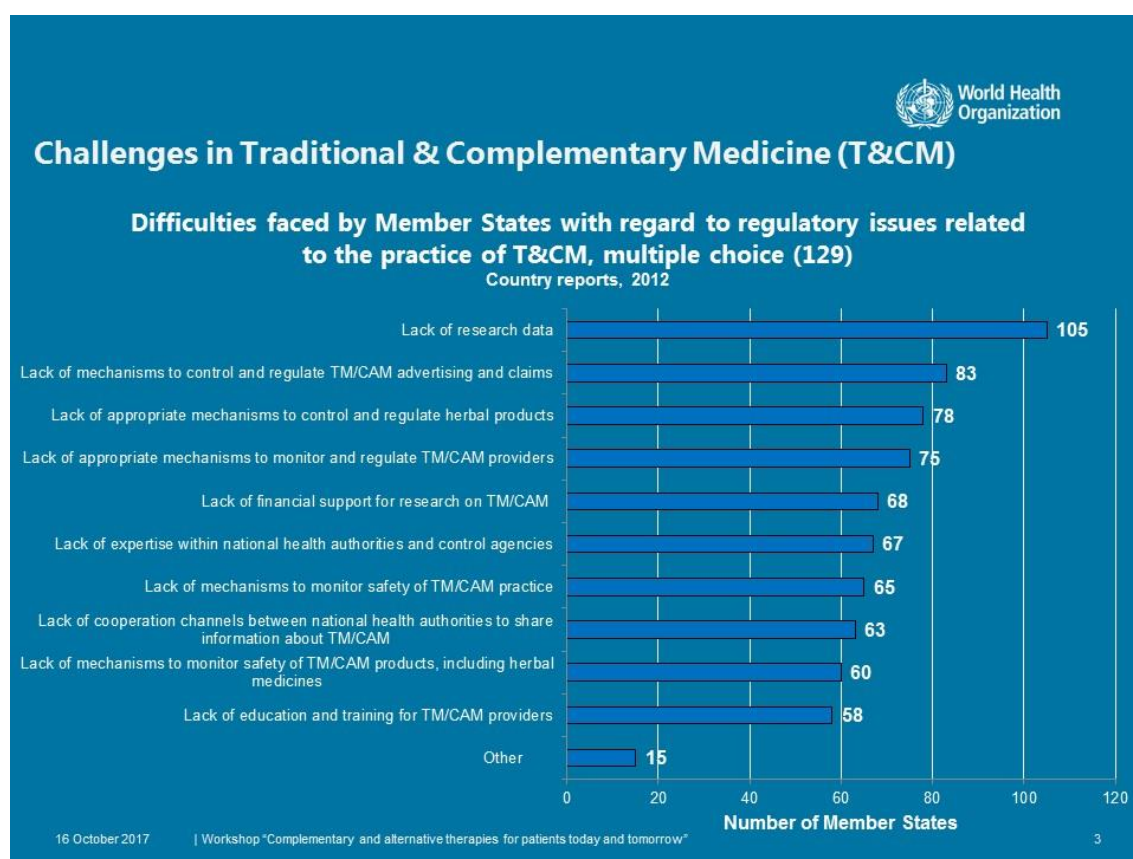
India - Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH)

Over 780,000 registered AYUSH practitioners

1 million (est.) village-based, traditional AYUSH community health workers

16 October 2017 | Workshop "Complementary and alternative therapies for patients today and tomorrow"

2



World Health Organization

WHO Traditional Medicine Strategy 2014-2023: Goals


- Harnessing the potential contribution of T&CM to health, wellness, people-centred health care and universal health coverage.
- Promoting safe and effective use of T&CM through the regulation, research and integration of T&CM products, practices and practitioners into the health system, as appropriate.



16 October 2017 | Workshop "Complementary and alternative therapies for patients today and tomorrow" 5

World Health Organization

WHO TM Strategy 2014-2023: Objectives and directions



- Build knowledge base for management through policies**
 - understand and recognize role and potential, build country profile
 - strengthen knowledge base, build evidence and sustain resources
- Strengthen quality assurance, safety, proper use and effectiveness by regulation**
 - products: monitoring, enforcement, harmonization
 - practices and practitioners: education & training, skills development, services and therapies
- Promote universal health coverage by integration**
 - capitalize on potential contribution to improve health services and health outcomes
 - informed choice about self-health care

16 October 2017 | Workshop "Complementary and alternative therapies for patients today and tomorrow" 6



WHA Resolution on Traditional Medicine

WHA67.18 adopted in May 2014 urges Member States :

- ❑ To adapt, adopt and implement, where appropriate, the WHO strategy as a basis for national T&CM programmes or work plans
- ❑ To develop and implement working plans to integrate TM into health services particularly primary health care services
- ❑ To report to WHO on progress in implementing the strategy



WHA Resolution on Traditional Medicine

WHA67.18 requests the Director General of WHO :

- ❑ To facilitate Member States' implementation of the WHO strategy, supporting their formulation of knowledge-based national policies, standards and regulations, and strengthening national capacity building
- ❑ To provide policy guidance to Member States on how to integrate T&CM services within health care systems
- ❑ To provide technical guidance in ensuring safety, quality and effectiveness of T&CM services



WHA resolution on Strengthening integrated, people-centred health services

WHA69.24 adopted in May 2016 urges Member States :

To **integrate where appropriate traditional and complementary medicine and modern health systems**, based on national context and knowledge-based policies, while assuring the safety, quality and effectiveness of health services and taking into account a holistic approach to health



Implementation of the TM strategy

- I. Leadership
- II. Research and knowledge
- III. Standards, norms and technical documents
- IV. Building institutional capacity
- V. Evidence-based policy and monitoring & assessing

Implementation of the TM strategy



I. Leadership

Integration of T&CM in national health systems including integrative medicine:

- Support Member States in their efforts
- Review and assess the existing models of integration in Member States to record best practices

Quality and safety:

- Quality improvement and safety of T&CM services (starting in acupuncture)
- Quality and safety on herbal medicines
- Qualified T&CM practitioners

Networking:

- International Regulatory Cooperation for Herbal Medicines (IRCH)
- WHO Collaborating Centres for Traditional medicine
- WHO Expert Advisory Panel for T&CM
- Professional associations in official relations with WHO

16 October 2017

| Workshop "Complementary and alternative therapies for patients today and tomorrow"

11

Implementation of the TM strategy



II. Research and knowledge

Clinical evidence:

- Database, platform
- Report on T&CM clinical evidence

T&CM Knowledge platform

Collaborative research projects

- Coordinate and support

16 October 2017

| Workshop "Complementary and alternative therapies for patients today and tomorrow"

12

Implementation of the TM strategy



III. Standards, norms and technical documents

Technical documents:

- Guidelines on quality and safety of herbal medicines under different topics/focuses
- Key technical issues for safe use of herbal medicines with reference to interactions with other medicines
- Methodology for clinical study in traditional medicine

International terminology and classification of T&CM:

- International terminologies in different T&CM systems/modalities
Ayurveda, Siddha, traditional Chinese medicine, Unani
- Web-based T&CM terminology with synonyms
- Traditional medicine chapter in ICD-11

Benchmarks for practice in T&CM:

- Acupuncture, Ayurveda, Panchakarma, Tuina, Unani

ICD-11

International Classification of Diseases for
Mortality and Morbidity Statistics
Eleventh Revision

2016 Edition for Member State comment
High level overview



16 October 2017 | Workshop "Complementary and alternative therapies for patients today and tomorrow"

Implementation of the TM strategy



IV. Building institutional capacity

Workshops:

- Series of interregional training workshops for capacity building of governmental officials

Capacity building tools:

- Benchmarks for training in T&CM, such as: Ayurveda, Naturopathy, Nuad Thai, Osteopathy, Traditional Chinese Medicine, Tuina, Unani
- Proposed Benchmark for training in Anthroposophic Medicine
- Currently developing Benchmarks for training in Cupping, Tibetan Medicine, Yoga

16 October 2017 | Workshop "Complementary and alternative therapies for patients today and tomorrow"

14

Implementation of the TM strategy



IV. Evidence-based policy and monitoring & assessing

Country support in the implementation of the WHO TM strategy

Information sharing

Monitoring the implementation of WHO TM strategy

Global surveys:

- Conduct regular global surveys for building a database as repository of Member States situation and assessing the trends of T&CM

16 October 2017

| Workshop "Complementary and alternative therapies for patients today and tomorrow"

15



Integration of Traditional & Complementary Medicine into National Health Systems

**The patients and public will benefit from both
Western medicine and T&CM.**

Thank you

WHO

20, Avenue Appia
1211 Geneva

Switzerland

Dr Stéphane Espinosa | Consultant | Traditional, Complementary and Integrative Medicine Unit, Department of Service Delivery and Safety

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT ECONOMIC AND SCIENTIFIC POLICY **A**

Role

Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

Policy Areas

- Economic and Monetary Affairs
- Employment and Social Affairs
- Environment, Public Health and Food Safety
- Industry, Research and Energy
- Internal Market and Consumer Protection

Documents

Visit the European Parliament website:
<http://www.europarl.europa.eu/supporting-analyses>

PHOTO CREDIT:
iStockphoto.com; Shutterstock/beboy



ISBN 978-92-846-2226-9 (paper)
ISBN 978-92-846-2227-6 (pdf)

doi:10.2861/260360 (paper)
doi:10.2861/169945 (pdf)

