CAMbrella

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1 Summary

This report describes legislation, Regulations and Resolutions in the European Union (EU) and the Council of Europe that may influence the professional practice of CAM, whether practised by an authorized/licensed health care provider or by a provider without such authorization/licensing. This system of European-wide legislation will also affect the conditions under which patients are receiving CAM treatment(s) in Europe.

We have found no direct EU legislation of CAM except for Directives concerning CAM medicinal products (to be described in WP2 report number 2). Two Resolutions deal with non-conventional medicine:

- ***The status of "non-conventional medicine". Resolution A4-0075/97***
  The European Parliament Resolution on how non-conventional medicine should be included more formally as a special field in the European legislation.
- ***A European Approach to non-conventional medicines. Resolution 1206(1999)***
  The Parliamentary Assembly of the Council of Europe Resolution on non-conventional medicine.

How legislation connected to "the Four Freedoms" is handled in EU/The European Economic Area (EEA) influences the individual states' national CAM legislation and legislation that impacts directly or indirectly on CAM. Of particular interest is how patients and health professionals are able to relate to diverse national CAM regulations. European CAM practitioners have different levels of training as a basis for their practice, whether they are formally licensed or not, and patients have varying expectations depending on experiences from their home country. This heterogeneous situation influences CAM patients' rights, access and potential safety, and constitutes a challenge to a harmonized national and European follow-up of the new Cross-border Healthcare Directive 2011/24/EU.

Harmonization of training and regulation of non-conventional disciplines is only marginally covered in the Directive 2005/36/EC Professional Qualifications. In many states only doctors or other health professionals are allowed to practise CAM according to national health regulation. The EU regulated professionals database includes only a few CAM professions in some member states. We have thus found that the Resolutions on the status of non-conventional medicine from 1997 and 1999 have not been followed up with harmonized CAM training or regulation.

The Council of the EU invites the Commission to integrate gender aspects in health policy and research. Research confirms gender-related differences in health and the use of CAM treatments. Further analyses on those aspects are needed to develop knowledge-based CAM regulation in the EU.

The European Parliament Resolution on non-conventional medicine from 1997 stated that non-conventional medicine disciplines should be clearly identified and defined. We have

found few overall clear distinctions between conventional and non-conventional medicine in the EU legislation. An adequate regulation and supervision of CAM professionals and CAM therapies will require special knowledge in the CAM field to take into account the special features of this field of health care. Developing the European legislation of CAM by simply adapting the criteria of conventional medicine will probably be inadequate for regulation of the CAM field.

The most important obstacles that hinder the European Parliament Resolution call for "a process of recognizing non-conventional medicine" are the Treaties of Rome and Lisbon clearly stating that the individual member state has the responsibility for "the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them". This legitimizes and sustains the wide variations in CAM regulation across Europe.

Another obstacle is the unwillingness of the individual European country to voluntarily harmonize their legislation and regulation of CAM with other European states. If this had been done to a larger degree, both patients and providers would be able to benefit from both "The right to move and reside freely" Directive, "The Professional Qualifications" Directive "The Cross-Border Healthcare Directive", as well as the Services and the Social Security Directives.

The European Parliament Resolution on non-conventional medicine from 1997 stated that non-conventional medicine disciplines should be clearly identified and defined. The Resolution also calls on the Commission "to launch a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees".

In contrast to this, the EU treaties have repeatedly established that health policies are a national responsibility for the member states even if several EU Directives, Regulations and Resolutions increasingly impact on how member states organize their national health policy and services.

The Cross-border Healthcare Directive, in particular, respects the established differences in national healthcare systems. It aims to remove obstacles to the fundamental freedoms that enable patients from one EU member state to choose to seek treatment in another EU member state and clarifies the responsibilities of EU member state health systems as providers to patients crossing borders. Regional collaboration between providers, purchasers and regulators from the different member states can ensure safe, high-quality and efficient cross-border healthcare at a regional level. Historical and cultural similarities between neighbouring countries would thus seem to potentially facilitate cross-border opportunities in the CAM area more than EU-wide Directives, Regulations and Decisions.

We think it is important to encourage individual states within culturally similar regions to voluntarily harmonize their CAM legislation and regulation. If this does not happen, and the EU sees such harmonization as valuable it might need to reconsider its general respect for member states' health care organizational diversity.

2 Introduction

The present report constitutes the CAMbrella project report number 3 of Deliverable D9, "Legal status and regulations of CAM in Europe". The report describes task 2.3. "Status and potential obstacles for EU-wide regulation of CAM". The report is provided by Work Package (WP) 2. EU-wide regulation of *CAM medicinal products* will be included in the *WP2 report 2* on regulation of medicinal products. This is due to the close connection between the EU-wide regulation and country-specific regulations of medicinal products(1).

Of special interest is how CAM-related issues are regulated at the EU/EFTA/EEA level and how those regulations influence national health legislation and regulation. Findings of national CAM legislation will be described in the WP2 report number 1 – legislation of CAM in 39 European countries.

At the EU/EFTA/EEA level CAM is only regulated indirectly through legislation affecting health-care related issues. This report will therefore make a comprehensive review of this general legislation and regulations. Some of the states included in the three CAMbrella WP2 reports are full EU members; others are affiliated to the EU through various legislation and agreements. This will determine how EU legislation and regulations influence the states' national legislation. This report will therefore present a short summary of the general EU regulatory systems and how the European states are linked to those systems.

3 Aim

The objectives covered in this report are to review at EU level:

- The status of EU-wide regulation of CAM practices.
- The potential obstacles for EU-wide regulation of CAM practices.

4 Methods

As an introduction we made a comprehensive overview of matters that may influence CAM in the European legislation. Descriptions of health issues, the legal and CAM terminology and the interaction between conventional medicine and CAM vary both in the European Union bodies and within the 39 countries included in this report. To address CAM-related legislation in the EU, we included both the EU legislation that influences the member states' national health legislation and various aspects of EU regulation of conventional medicine.

A search was performed in the web sites/databases **EUROPA and EUR-lex** to identify the European Union official law documents. We searched for information about EU Directives and Regulations regarding CAM, and their EU/EFTA/EEA implications. We also included items on other health issues, including legislation in progress, relevant for CAM. In addition we searched for Decisions, News, Resolutions and relevant Information from the European Commission, the European Parliament and the Council of Europe.

A personal visit was made to **the European Union offices and NGO bodies in Brussels** to establish firsthand, updated information and perform a quality check on the findings from the literature search. Meetings were held with:

- **Counsellor for health and food safety at the Mission of Norway to the EU**.
- **The European Commission Central Library**.

At the Mission of Norway to the European Union we received updated information mainly on the EFTA/EEA legal connection to EU legislation and the new Cross-border Healthcare Directive 2011/24/EU. The European Union Commission Library assisted in searching for CAM legislation documents.

Meetings with the following NGOs gave important additional CAM information:

- **IVAA** (International Federation of Anthroposophic Medical Associations) and **ICMART** (International Council of Medical Acupuncture and Related Techniques) - EU Liaison Office.
- **AESGP** (The Association of the European Self-Medication Industry).

At AESGP we received information about the EU regulation of medicinal products. Regulation of CAM medicinal products will be reported in the CAMbrella project WP2 Report No. 2.

We have also collected information from the **European CAM associations/coalitions** and other **CAMbrella stakeholders** (Listed in attachment 1).

4.1 Countries included in the report and their legal connection to EU

This report covers 27 EU member states as well as 12 associated states. Each state is influenced by the EU legislation and has adjusted their national legislation depending on their connection to EU.

4.1.1 The European Union includes 27 member states

12 states became members in 1993 (Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, United Kingdom).

3 states left EFTA and became members of EU in 1995 (Austria, Finland, Sweden).

10 states became members of EU in 2004 (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia).

2 states became members of EU in 2007 (Bulgaria, Romania).

It is of special interest *to know if and how national CAM-related legislation has changed in the 12 member states joining EU in 2004 and 2007 in response to health- and medicinal-related Directives and Regulations in the EU. It is also of interest to see if the original EU*

member states have a more homogenous CAM legislation than the new EU member states (to be described in WP2 report 1).

4.1.2 EFTA - The European Free Trade Association includes 4 states

In 2011 EFTA includes Iceland, Liechtenstein, Norway and Switzerland.

Most important for the CAM *legal and regulatory area is that EFTA and the EFTA member states amend their national legislation in accordance with EU legislation to a certain extent. However, most of the EU legislation of interest for CAM is approved unchanged in the EEA legislative system. Since all the EFTA countries except Switzerland have joined EEA, the specific EFTA legislation will not be reviewed in this report. For EEA details, see below.*

4.1.3 EEA - The European Economic Area

EEA unites the **27 EU member states** and **3** of the 4 **EFTA States** (Iceland, Liechtenstein and Norway) in an Internal Market. Switzerland (EFTA member state) enters into bilateral agreements with EEA in some areas. Free trade agreements have been signed between EFTA/EEA and Turkey, Israel, Macedonia, Croatia, Albania and Serbia (among others).

4.1.4 The European Commission Seventh Framework Programme (FP7) (8 states)

The following **8 additional countries** are included in this report since they are connected to the FP7 research programme by the following **third country agreements**:

- **Israel** (EC) – the Science and Technology Agreement 2007
- **Croatia, the Former Yugoslav Republic of Macedonia, Montenegro* and Turkey** (EC)/candidate countries, "Memorandum of understanding"
- **Albania, Bosnia & Herzegovina, Serbia** (EC)/potential candidate countries, "Memorandum of understanding"

*Montenegro was at the starting time of CAMbrella a potential candidate country.

Note:

The EFTA countries **Iceland, Liechtenstein and Norway are connected to FP7 through** - Article 1 of protocol 31 of the **EEA agreement** amended on 15 June 2007 by a decision of the EEA Joint Committee.

The EFTA country **Switzerland** is **connected to the FP7 programme** with the following agreement: ((European Commission (EC) and Euratom (nuclear weapon)) The Science and Technology Agreement.

Table 4-1 Country membership (X) to EU/EEA/EFTA, Council of Europe and FP7 (Seventh Framework Programme)

Countries	EU	EEA	EFTA	Schengen	The Council of Europe
Albania	Potential candidate, FP7		Trade agreement		X
Austria	X 1995	X		X 1997	X
Belgium	X	X		X 1995	Founding member (FM)
Bosnia and Herzegovina	Potential candidate, FP7				X
Bulgaria	X 2007	X			X
Croatia	Candidate, FP7		Trade agreement		X
Cyprus	X 2004	X			X
Czech Republic	X 2004	X		X 2007	X
Denmark	X	X		X 2001	FM
Estonia	X 2004	X		X 2007	X
Finland	X 1995	X		X 2001	X
France	X	X		X 1995	FM
Germany	X	X		X 1995	X
Greece	X	X		X 2000	X
Hungary	X 2004	X		X 2008	X
Iceland	Candidate, FP7	X	X	X 2001	X
Ireland	X	X			FM
Israel	FP7		Trade agreement		-
Italy	X	X		X 1997	FM
Latvia	X 2004	X		X 2007	X
Liechtenstein	FP7	X	X		X
Lithuania	X 2004	X		X 2007	X
Luxembourg	X	X		X 1995	X
Macedonia	Candidate, FP7		Trade agreement		X
Malta	X 2004	X		X 2007	X
Montenegro	Candidate, FP7				X
Netherlands	X	X		X 1995	FM
Norway	FP7	X	X	X 2001	FM
Poland	X 2004	X		X 2007	X
Portugal	X	X		X 1995	X
Romania	X 2007	X			X
Serbia	Potential candidate, FP 7		Trade agreement		X
Slovakia	X 2004	X		X 2007	X
Slovenia	X 2004	X		X 2007	X
Spain	X	X		X 1995	X
Sweden	X 1995	X		X 2001	FM
Switzerland	FP7	bilateral agreements	X	X 2008	X
Turkey	Candidate, FP7		Trade agreement		X
United Kingdom	X	X			FM

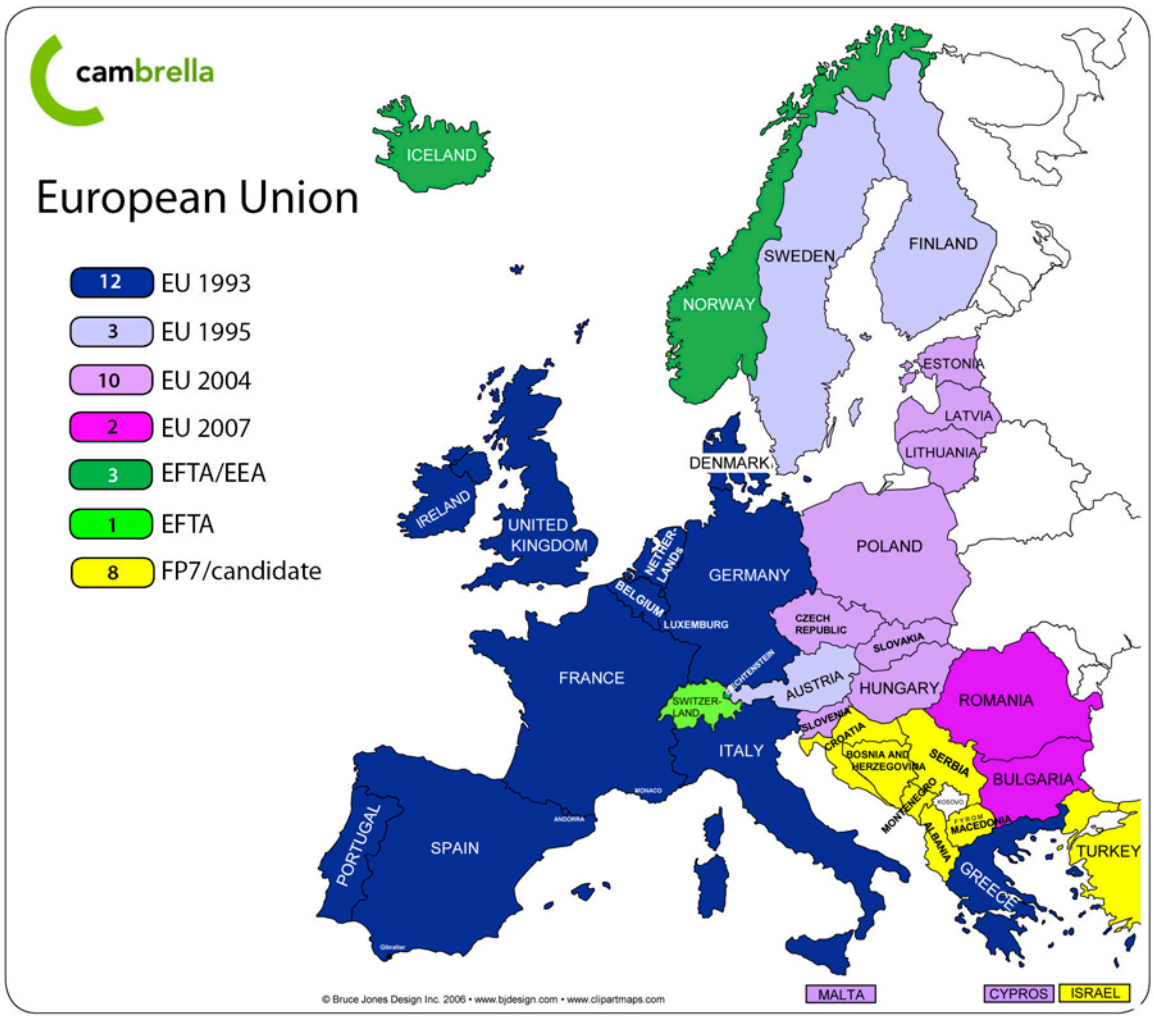

Figure 4-1 Country relationship to the European Union

5 The EU/EFTA legal and regulative system

The European Union Law operates alongside the legal systems of the individual EU member states and consists of Treaties and Laws (Directives, Regulations, Decisions (Court Judgments)). The EU legislation is **based on the EU treaties** and the **legislative acts** are expressed through **Regulations, Directives or Decisions.**

The EU and EFTA countries (including candidate countries) relate to these levels of legislation that may influence CAM[1] (Complementary and Alternative Medicine) in addition to national legislation.

[1] EU uses the notion ”non-conventional medicine”

5.1 The EU Treaties

The legislation of interest for this report is mainly based on the 1958 Treaty of Rome followed up by **the 2007 (Entered into force December 1, 2009) Treaty of Lisbon** with **the Four Freedoms** (the requirements that goods, services, capital and persons **are to move freely** within the EEA); article 168 includes common safety concerns and measures setting high quality standards for public health, quality and safety for medicinal products and devices for medical use, research and cross-border areas.

The EU Treaties have repeatedly established that health policy is **a national responsibility** for the member states. This is adjusted and confirmed in the Lisbon Treaty[2](2) in TITLE XIV Public Health Article 168 number 7:

"7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood."

This statement is important to keep in mind when describing legislation and regulation of CAM in the European Union. Despite this statement, several EU Directives and Regulations do influence how the member states organize their national health policy and services.

5.2 The Regulations, Directives and Decisions

Directives, Regulations and Decisions have effect within the EU's member states either with local adjustments to national legislation or precedence over national legislation. The EU Parliament non-legislative Resolutions are recommendations and political statements only.

EU Regulations are adopted by the Council and considered as directly enforceable law in all the member states. Regulations do not need to be implemented into national legislation, because they come into force immediately on publication. They cover general measures that are binding for all states. (Note: National regulations within the member states are not the same as EU Regulations).

EU Directives are addressed to the member states and are intended to align national legislation. How the individual member states implement the Directives in national legislation is left to the member states.

EU Decisions refer to decisions taken by the European Court of Justice and address individuals. These are automatically binding upon those individuals (individuals and member

[2] OJ C 306 17.12.2007, p. 01

states) to which they are addressed, but can have a potential influence in creating new EU legislation or modifying existing EU legislation.

Of interest for CAM *is how the different implementations of EU legislation both in time and content influence variations in regulation of CAM practices and patients' rights and safety in the member states*.

5.3 EEA - legislation and procedures

The EEA agreement is based on the EU treaties (e.g. Treaty of Rome, Treaty of Lisbon), legislation (EEA relevant Regulations, Directives, Decisions) and on certain non-binding instruments adopted by the EU institutions on an on-going basis)(3).

The EU "Treaty of Lisbon" with "**the four freedoms"** is included in the EEA agreement. "**The four freedoms"** aim to enable goods, services, capital and persons **to move freely** within the EEA. **Education, training, employment, enterprise and civil protection** are among the fields that are handled within EEA. Relevant legislation is incorporated into the EEA agreement by decisions of the **EEA Joint Committee**. The non-EU EEA member states can negotiate adaptations to EU legislation, while for the EU countries the EU legislation is already binding.

The non-EU EEA member states have not transferred national legislative competences to the EEA institutions. Consequently, Iceland, Liechtenstein and Norway amend the EU/EEA Directives to national legislation in the same manner as the EU member states. Regulations and Decisions are automatically binding for the EU member states and individuals without national legal amendments. However, for the non-EU EEA member states such documents have to be amended to national legislation.

Of interest for CAM is *how* ***"the four freedoms"*** *are handled in EEA and* ***whether the Regulations, Directives and Decisions influence the member states' national CAM-related legislation differently****. In the CAMbrella reports 1 and 2 we will look for potential national legislation regarding CAM practices, treatments, medicinal products and patients' rights and safety, which is connected to or based on EU legislation.*

5.4 EU Directives, Regulations and Decisions of importance for CAM

In this chapter we will list the legal documents passed in the European Union with potential impact on CAM legislation in EU/EFTA/EEA. The content of each document is thereafter described from a CAM perspective.

- **"The Schengen Agreements". DIRECTIVE 2004/38/EC**[3] (4)
  of the European Parliament and of the Council of 29 April 2004: on the right of citizens of the Union and their family members to move and reside freely within the territory of the member states.

[3] OJ L 158, 30.4.2004, p.77-123

- **Social security, REGULATION (EC) No 883/2004[4] (5)**
  of The European Parliament and the Council of the European Union of 29 April 2004 on the coordination of social security systems.
- **"The Service Directive", DIRECTIVE 2006/123/EC[5] (6)**
  of the European Parliament and of the Council of 12 December 2006: on services in the internal market.
- **Professional Qualifications, Directive 2005/36/EC[6] (7)**
  of 7 September 2005 on the recognition of professional qualifications (Text with EEA relevance). The Directive included in this report is **amended up to 24 March, 2011[7](8).**
- **The Cross-border Healthcare Directive 2011/24/EU[8] (9) ("The Patient Rights Directive")**
  of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

5.5 The right to move and reside freely- Directive 2004/38/EC[9](4)

The Directive 2004/38/EC(4) was brought into force within the member states by 30 April 2006 and gives detailed regulations of the right to move and reside freely in the EU.

Free movement of individuals and family members within the member states is one of the 4 pillars of the EU and is a fundamental right of EU citizens. They can stay in another country for 3 months unconditionally. The right is conferred directly by the Treaty, and is not dependent upon administrative procedures. After 5 years of staying in another EU country they can acquire the right of permanent residence. Workers or self-employers have the right to stay up to 5 years when employed or self-employed.

Citizens from other member states shall be given access to equal treatment as nationals in areas covered by the Treaty and secondary legislation. The right of free movement implies that individuals observe the laws of their host country, and restrictions can be given on grounds of public security or public policy. Persons who commit crimes in the host member state are subject to the same consequences as the citizens of that member state.

Of interest for CAM is *how patients and health professionals are informed of and able to adjust to the national CAM regulations in the EU member states when moving to or travelling between countries in Europe. Practitioners will have different CAM training as a basis for their formal professional licence, and patients will have different expectations depending on what they are accustomed to in their home country. This may influence CAM practices and*

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[4] OJ L 166, 30.4.2004, p.1
[5] OJ L 376, 27.12.2006, p.36
[6] OJ L 255, 30.9.2005, p.22
[7] 2005L0036 — EN — 24.03.2011 — 006.001 — 1
[8] OJ L 88, 04/04/2011, p. 0045 – 0065
[9] OJ L 158, 30.4.2004, p. 77–123

patients' treatment services. Because of the heterogeneity of the legal situation facing CAM in EU member states it is currently not possible for CAM practitioners to move freely between member states in order to practise professionally.

5.6 Professional Qualifications, Directive 2005/36/EC[10] (7)

The Directive 2005/36/EC came into force in 2007. Included in this report are amendments **up to 24 March, 2011[11](8)**. The Directive is an important legal basis for free movement of professionals in Europe. A profession is considered regulated when access to it and the exercise of it are subject to the acquisition of a specific professional qualification.

Chapter I of Title III of Directive 2005/36/EC sets out the general system for the recognition of documentation of training for the purpose of establishment in the host country(10). Professional qualifications are grouped into five levels (see Article 11). Under certain restricted conditions (see Article 14), the host country may impose compensation measures, i.e. an adaptation period of up to three years or an aptitude test(10).

Substantial differences between countries regarding training requirements for a given profession can be compensated for if the professional meets a set of qualification criteria known as a 'common platform'. No common platform has been adopted yet(10).

The European Commission database of regulated professions in the EU Member States, EEA countries and Switzerland is covered by Directive 2005/36/EC. The database includes among others the professions falling under the "General System" of mutual recognition of professional qualifications and the "Sectorial professions" benefiting from automatic recognition on the basis of harmonization of minimum training conditions: doctors, nurses, midwives, pharmacists, dentists, veterinary surgeons and architects(10). The database contains professions regulated in the Member States. Detailed conditions for recognition of professional qualifications are found in the Directive 2005/36/EC and its annexes.

Some of the member states have a few CAM professions registered in the EU regulated professions database. Details will be described in CAMbrella report number 1 concerning each state's national CAM legislation.

Of special interest for CAM *is that we have* ***not found*** *that* ***harmonization of training*** *for CAM professionals constitutes a special focus in the Directive 2005/36/EC Professional Qualifications (7). According to the national health regulation, several member states only permit doctors or other health professionals to practise CAM. Other member states have unilaterally introduced legislation regulating CAM practice by non-licensed health practitioners. We have not found that the Resolution on status of non-conventional medicine*

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[10] OJ L 255, 30.9.2005, p.22

[11] 2005L0036 — EN — 24.03.2011 — 006.001 — 1

from 1997 has been followed up with harmonized training in CAM. See further comments below.

5.7 Patients' rights in cross-border healthcare Directive 2011/24/EU[12] (9)

The Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 concerns the application of patients' rights in cross-border healthcare(9).

The Directive supplements the legislation on the coordination of social security schemes (Regulation (EC) No 883/2004) and aims at facilitating access to safe and high-quality cross-border healthcare and cooperation on healthcare between the member states. At the same time the preserving of member states' rights to organize their own healthcare system stands unchanged. The Directive comes into force in national member states' legislation within October 25, 2013, and there are still several unsolved challenges.

When introducing the cross-border healthcare Directive one expects a uniform and coherent health legislation framework for all citizens in Europe. The Directive covers both public and private providers, and patients will have access to information on the quality and safety of the care they will receive. Within specific boundaries it is stated that:

- For hospital care a patient should be free to choose which healthcare provider to use.
- For non-hospital care the patient can seek healthcare abroad without prior authorization or formalities, and claim reimbursement when returning to the home country.
- Medical products prescriptions will be recognized throughout the EU provided that the product has a market authorization and is available in the country.

The Directive emphasizes the patients' rights to access safe and high quality treatment and to be reimbursed for it. Patients shall enjoy equal treatment with the citizens of the country in which they are treated and the treatment shall be based on quality and safety standards of healthcare (Memo/11/32 Brussels 19 Jan 2011 Press release).

Rules on information and assistance to patients, and guidelines on how national legislation will be affected, will be developed (EU Commission 2 July 2008).

5.7.1 Reimbursement of cross-border healthcare treatment

The cross-border healthcare Directive regulates patients' rights to reimbursement of treatment received in other member states of EU/EEA. It shall not influence on the rights according to regulation EC NO 883/2004 –27 (social security) of refund of cost of healthcare when temporarily staying in another member state.

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[12] *OJ L 088 , 04/04/2011 P. 0045 - 0065*

Reimbursement will be given according to the following guidelines:

- The reimbursed amount will be equal to the cost in home state for the same type of healthcare.
- The member states must inform patients about the reimbursement tariffs.
- Treatment abroad can be reimbursed when not available in the home country.
- Reimbursement will correspond to the national "health benefits package".

Prior authorization from home state is necessary:

- For healthcare which involves overnight hospital stay of at least one night.
- For highly specialised and cost-intensive healthcare.
- In serious and specific cases where the quality or safety of the care provided abroad can be questioned.

Authorization can be refused

- If the treatment or healthcare provider could represent a risk for the patient.
- If the healthcare can be provided at home within reasonable time (This decision must be explained by the member state).

The cost of the chosen health care must be paid upfront by the patient. Member states can choose to confirm the amount they will reimburse in writing before the treatment is given.

Of special interest *is how the cross-border healthcare legislation in the member states and in the EU will influence CAM practitioners and patients' rights in relation to CAM treatments. To clarify this, every issue pointed out by the Parliament and the Council of the European Union regarding this Directive could be described from a CAM perspective.*

6 EU Resolutions, Information and Questions of importance for CAM

In this chapter we list EU Resolutions, Information and Questions of interest for CAM. Thereafter we describe the content of the documents with a CAM perspective.

- **The status of "non-conventional medicine". Resolution A4-0075/97[13] (11)**

  The European Parliament Resolution on how non-conventional medicine should be included more formally as a special field in the European legislation.

- **Common values and principles in health systems, 2006/C 146/01 I (Information) Council 22.6.2006 C 146/1[14](12).**

  The Council of the European Union conclusions on Common values and principles in the European Health Systems.

[13] OJ C 182, 16/06/1997 P. 0067

[14] 2006/C 146 01

- **Women's health. 2006/C 146/02 I (Information) Council 22 June 2006 C 146/2[15](13).**
  The Council of the European Union conclusions on women's health.
- **Question from The Greek Association of Homeopathic Medicine, 2001[16](14).**
  A question forwarded to the Commission about recognition of doctors practicing homeopathy.
- **Question about Naturopathy from Christina Muscardi, 17 June, 2002[17](15).**
  A question forwarded to the Commission regarding the recognition of naturopathy.

6.1 Resolution on the status of non-conventional medicine. OJ C 182, 16/06/1997 P. 0067[18] (11)

The European Parliament in this Resolution indirectly calls on the Commission to formulate European legislation in the area of **non-conventional forms of medicine.** They outlined specific areas that should be emphasized and linked to the legislation. Areas of importance were connections to conventional medicine, regulation and training of health professionals, medicinal products and European citizens' rights and consumer protection.

"Non-conventional medicine" was previously used as the EU term for "alternative medicine", "natural medicine" and "complementary medicine". In the EU FP7 R & D Framework programme 2008-2012 and the current EU Health Framework programme 2008-2013 the term used is "complementary and alternative medicine". *(Remark: in the CAMbrella reports the notion is mostly "complementary and alternative Medicine (CAM)).*

The Resolution underlined that the suggested activities on non-conventional medicine should focus on legislation and research on:

- Quality and safety of non-conventional medicinal products; including homeopathic medicinal products and food supplements.
- The effectiveness and regulation of other therapeutic methods than conventional therapies, **"in particular chiropractic, homeopathy, anthroposophic medicine, Chinese traditional medicine (including acupuncture), shiatsu, naturopathy, osteopathy, phytotherapy, etc."**
- Making a clear distinction between alternative and complementary non-conventional medicine disciplines.
- Developing harmonized forms of legislation and recognition of non-conventional medicine at the European level and within the member states.

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[15] OJ C 146 22.6.2006

[16] E-2297/01

[17] E-1734/02

[18] OJ C 182, 16/06/1997 P. 0067

With regard to health professionals (doctors mentioned specifically) the Resolution emphasizes the right to provide the treatment that they think will be the best for their patients. The Resolution outlines that the Treaties' rights on free movement of persons and freedom of establishment in the member states should not be limited by heterogeneous regulation of non-conventional medicinal therapies and providers.

The Resolution underlined the patients' rights to choose treatment, to be protected against unqualified individuals, to be guaranteed maximum safety and have access to accurate information.

The development of the legislation in this field in the European Union is described below. See particularly the EU legislation on ***the right to move and reside freely - Directive 2004/38/EC[19](8)*** *and* ***The Cross-border Healthcare Directive. /2011[20](“The Patient Rights Directive”) (9).***

The Resolution established that non-conventional medicine disciplines should be clearly identified and defined. Consequently the legislation in the European bodies and in the member states' **national legislation** should be developed so they would become **more homogeneous**. To outline the development on this issue the national regulation of some of the main treatments mentioned above is described in the CAMbrella project WP1 report 1 “Legal, regulatory, supervisory and reimbursement status for each member state and the associated states”.

The Resolution stated that **training criteria** for non-conventional medical providers should be **harmonized,** and training of conventional health professionals should include an introduction to non-conventional disciplines. **Mutual recognition of qualifications** of health personnel in Europe has been developed through ***Directive 2005/36/EC[21] Professional Qualifications, (7),*** *but does not make any specific reference to CAM disciplines.*

The Resolution emphasises research on effectiveness and safety of non-conventional medicine therapies and medicinal products. Directives of importance are **Directive 2001/83/EC[22](16)** relating to medicinal products for human use, Directive 2004/24/EC[23](17) as regards traditional herbal medicinal products[24] and Directive 2002/46/EC on food supplements[25](18). Development of the European legislation on medicinal products and

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[19] OJ L 158, 30.4.2004, p. 77–123
[20] 2008/0142 (COD)
[21] OJ L 255, 30.9.2005, p.22
[22] OJ L 311, 28.11.2001, p.67
[23] OJ L 136 30.4.2004, p.85
[24] Amended Directive 2001/83/EC
[25] OJ L 183, 12.7.2002, p. 51

food supplements will be described in the CAMbrella WP2 Report number 2 on CAM medicinal products.

Note that this Resolution is merely an indication of where the parliament would like the EU to move in the future. The Lisbon treaty still stands: "***. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care".***

6.2 Common values and principles in health systems, 2006/C 146/01 I (Information) Council 22.6.2006 C 146/1[26](12)

"The Council of the European Union conclusions on Common values and principles in European Health Systems" is an Information statement by the 25 Health Ministers of the European Union, built on discussions that have taken place in the European Council and with the Commission. The Council notes in this Information that the Commission has decided that healthcare services are exempt from the scope of the Directive on services in the internal market. There is a need to clarify the interaction between the EC Treaty provisions on the free movement of services and the health services provided by national health care systems.

The Council notes that the member states have different approaches regarding treatment reimbursement, payment and equity; terms of the rights of patients as well as obligations of healthcare providers. The document establishes that the member states should provide good quality care through training of healthcare staff based on clearly defined national standards to ensure best practice.

The Council underlines that an important part of the agenda relates to the principle of safety. There must be a systematic approach to ensure patient safety including monitoring risk factors, adequate training for health professionals and control with misleading advertising of health products and treatments. Emphasis must be given to evidence and ethics.

Finally the document confirms that the member states should work together through the Commissions High Level Group on Health Services and Medical Care or Open method of Coordination on healthcare and long-term care to standardise the health systems. The Council concludes in this Information that health systems are a fundamental part of Europe's social infrastructure.

A question for CAM is whether or not *the "Common values and principles for European Health Systems"* ***apply to CAM services****. These services are differently regulated in the European member states and many CAM services are not formally recognized or regulated as*

[26] 2006/C 146 01

"healthcare services". Consequently, if CAM treatment is not included in "healthcare services" the Common values will be very differently integrated in the European countries.

6.3 Women's health. 2006/C 146/02 I (Information) Council 22.6.2006 C 146/2[27](13)

"The Council of the European Union conclusions on women's health" is an Information statement looking into the health status of women, gender specific data on health and the relationship between gender and health. The Council of the European Union invites the Commission to integrate gender aspects in health policy and research.

A number of research studies confirm a higher prevalence of CAM use among women and gender-related differences in health and the use of different CAM treatments.

***Of interest for CAM** is to **further analyse the differences of CAM use between men and women,** how this is taken into consideration and possibly influences CAM legislation, reimbursement, CAM practices and patient treatment choices in Europe.*

6.4 Question from The Greek Association of Homeopathic Medicine, 2001[28](14)

The Greek Association of Homeopathic Medicine addressed in 2001[29](14) a question to the Commission about recognition of doctors practicing homeopathy. They asked how the Commission intended to ensure terms of equality throughout the European states for doctors practising homeopathy. The answer confirmed that the member states are free to organize the recognition of health professionals on its own territory. To initiate harmonization of professions on a European level three conditions have to be met:

- "*A high level of consensus among the representative professional associations*
- *Support from a large majority of member state authorities*
- *Certainty that such an initiative will significantly add value to the existing system of recognition.*
- *And unanimity within the Council would also be required before a text can come into force at European level*".

None of these conditions have been met, concluded the Commission in 2001.

6.5 Question about Naturopathy from Christina Muscardi, 17 June, 2002[30](15)

Christina Muscardi forwarded a question to the Commission on 17 June, 2002[31](15) regarding the recognition of naturopathy. The question described the increasing use of alternative medicine and numbers of practitioners that provide such treatment and asked:

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[27] OJ C 146 22.6.2006

[28] E-2297/01

[29] E-2297/01

[30] E-1734/02

[31] E-1734/02

"In which countries is the profession of naturopathy legally recognized? Is there a European form of recognition? If not, could it consider it useful and appropriate to take steps to promote the recognition…?"

The Commission answered in the same direction as in 2001(homeopathy question); "no widespread consensus exists of at least some of the activities concerned (acupuncture, homeopathy, phytotherapy, naturopathy) and no coordination exists of the conditions of education and training of CAM professionals at the Community level" The Commission mentions that **22 different titles of physiotherapist** are regulated in the European countries.

The Commission **defines a profession to be regulated** "when there is an **administrative, regulatory or other legal requirement to hold a diploma or other occupational qualifications** in order **to pursue the profession** in question". Finally in the answer the Commission re-confirms that also the recognition of treatments lies with the member states.

7 The Council of Europe

The Council of Europe is not included in the European Union legislative system. However, they have passed one **CAM Resolution in 1999** as a follow-up of the European Parliament Resolution on the status of non-conventional medicine from 1997(11);

A European Approach to non-conventional medicines. Resolution 1206(1999) (19).
The Council of Europe is "an international organization in Strasbourg which comprises 47 countries of Europe. It was set up to promote democracy and protect human rights and the rule of law in Europe"(20). Except for Israel, all the countries included in the WP2 CAMbrella reports are members of the Council of Europe**.**

The Parliamentary Assembly outlines in the Resolution 1206(1999) 8 points on how non-conventional medicines should be met with a common approach in Europe. At the same time as they confirm the importance of preserving national legislation, they encourage the recognition of non-conventional medicines and the patients' freedom of choice in European health care. The Resolution supports the European Parliament **Resolution A4-0075/97[32] The status of "non-conventional medicine"(11)(see below)** which emphasizes the importance of research programmes especially on safety and effectiveness of CAM medicines.

The importance of professional training is discussed in the Resolution, both for doctors and for other practitioners of non-conventional medicines. University courses and official recognition are pointed out as important efforts to strengthen this field.

[32] OJ C 182, 16/06/1997 P. 0067

8 Discussion on CAM aspects related to EU/EFTA/EEA legislation and regulations

In the report we have pointed out legislation, Regulations and Resolutions in the European Union and the Council of Europe that may influence the professional practise of CAM, whether practised by an authorized/licensed health care provider or by a provider without such authorization/licensing. This system of European-wide legislation, Regulations and Resolutions will of course also affect the conditions under which patients are receiving CAM treatment(s), of which patient safety is central.

8.1 Basic framework of European CAM treatment

Although the Regulations and Directives listed in this document all influence indirectly the practice of CAM in Europe, the intention of the European Parliament outlined in its 1997 Resolution(11), has not been achieved. The calls on the Commission given in the Resolution have only partly been implemented.

8.2 The Treaty of Lisbon – basic framework of EU health regulation

The basic framework of EU regulation reformulated in the 2007/2009 Treaty of Lisbon stands unchanged: ***"Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care"***. With CAM seen as a part of health policy and/or "health services and medical care" in each individual EU member state, the (lack of) EU regulation influences the **treatment choices** for patients seeking CAM.

8.2.1 Treatment offered

Due to the individual state's responsibility for the organization of health care, European citizens experience a diverse situation with regard to how CAM treatments are offered.

In some countries (for example Germany, Hungary and France) only authorized/licensed personnel can legally treat patients. This means that patients can assume that the treatment providers are either conventional health care workers or are treatment providers with a separate CAM authorization/license. These approvals follow the fulfillment of requirements outlined by the countries' health authorities. Providers operating outside of this system of authorization/licensing are not allowed to treat individuals with health conditions, and sometimes operate as "health counsellors".

At the other end of the spectrum we find Norway where, in principle, treatment providers can practise without any professional qualification at all. In Norway CAM can be offered by anyone ranging from an authorized/licensed conventional health care worker (with a few limitations), through a well-educated CAM provider, to a common citizen without any qualification.

Anyone will understand that this widely differing system of regulation raises serious challenges when patients are to be ensured "access to safe and high-quality cross-border

healthcare and cooperation on healthcare between the member states" according to the Cross-border Healthcare Directive. Patients seeking CAM treatments will, in particular, find the systems so different that any expectation of patient autonomy is unrealistic.

8.2.2 Treatment sought

In conventional medicine there is a relatively high level of predictability with regard to which health professions a patient can gain access to across Europe. The Professional Qualifications Directive established an automatic recognition on the basis of harmonization of minimum training conditions for doctors, nurses, midwives, pharmacists and dentists within the health care system.

In the CAM sector there is some mutual recognition according to the "General System" in the Directive, but patients cannot expect to find the provider of their choice as an authorized/licensed treatment provider in all European countries. They might not even find that the treatment modality they are seeking exists at all in the country they are visiting or moving to.

Realizing that a substantial proportion of European citizens at any one time are seeking CAM treatment, it seems strange that a culturally homogeneous continent like Europe can accept this extremely unpredictable situation for its citizens.

8.2.3 Reimbursement

In Europe insured persons are covered by Article 2 of Regulation (EC) No 883/2004 on the coordination of social security systems(5) (nationals of a third country are covered by Regulation (EC) No 859/2003). Limitation of treatment under the Cross-border Directive should be without prejudice to the member states' obligations under **Regulation (EC) No 883/2004 of The European Parliament** and of **the Council of 29 April 2004[33](5)** on the coordination of social security systems.

If the patient is in a country temporarily and gets sick the reimbursement of treatment costs follows the regulations in the social security systems. If the patient has travelled to another country with the aim to receive treatment following the Cross-border Healthcare Directive(9) the reimbursement will follow the home states' regulations, but this reimbursement will normally only happen after the patient has paid up front.

This system is, however, not directly transferable to CAM. The reimbursement systems of CAM treatments differ widely between the states. Cross-border CAM treatments are currently mostly for patients that can afford the cost of travelling and paying the costs themselves with only partial or no reimbursement in the home state. This means that patients must know how CAM is regulated in the relevant countries according to the Cross-border healthcare or Social Security Directives. However, these two insurance and

[33] OJ L 166, 30.4.2004, p.1

reimbursement systems are not coherent. The member states can limit reimbursement relating to the quality and safety of the healthcare provided. CAM treatment is generally less documented than conventional medicine and CAM is in many countries not included in the national health supervision system. This means that reimbursement of CAM treatment can be refused because regulation of CAM in the country of affiliation differs from the country of treatment.

The current system, as we see it, is not designed to accommodate CAM treatments. European citizens must assume that CAM treatment received beyond their home legislation has to be covered out-of-pocket.

8.2.4 Safety

The member states have not harmonized their regulatory systems for responding to harm and protection of patients. This includes protection of personal data. CAM treatment is in some countries regulated and supervised as part of the conventional health care system, in other countries not. Consequently how a patient is handled when safety issues arise in connection with CAM treatment is, not surprisingly, also very different between the European member states.

8.3 Consequences of (lack of) EU regulation on clinical practice of CAM

It is difficult to see how the regulations influence CAM treatments. Is a consequence of this that harmonization of CAM regulations in Europe is a necessary pre-condition for improvement of the patients and CAM providers' access to correct information and safe treatment?

8.3.1 Authorized/licensed health care providers

Directive **2005/36/EC 7 September 2006[34](8)** on the recognition of professional qualifications influences the provision of CAM treatment in Europe. Providers of healthcare can work in all the European states under the **DIRECTIVE 2004/38/EC[35]** (4) (Rights of Union citizens to move and reside freely). The free movement of persons and services within conventional medicine has been achieved by a mutual recognition of medical qualifications. EU-wide approval of education and certificates are regulated in the **Directive 2005/36/EC(8)** (Amended up to March 2011) for selected health professionals. Included are medical doctors, nurses, midwives, dentists, veterinarians, pharmacists and physiotherapists (for some countries).

For medical doctors the Directive 2005/36/EC(8) facilitates the mutual recognition of conventional medical qualifications (basic training, additional training as general practitioners or medical specialists, if applicable). The system does, however, not recognize their possible additional qualifications in specific CAM therapies. A European-wide

[34] 2005L0036 — EN — 24.03.2011 — 006.001 — 1

[35] OJ L 158, 30.4.2004, p.77-123

recognized medical CAM specialty is not viable at the moment because the length of the existing specialised training courses is less than 3 years of full-time training, and, as stipulated by article 26 of this Directive, new medical specialties can only be included if they are common to at least two fifths of the member states.

The authorized/licensed health care providers with or without a local specialty can practise CAM in another state according to legislation in that specific country. However, such practice is sometimes impossible due to the heterogeneous regulation in Europe.

Obstacles can be:

- Authorizations and licences allowing the practice of CAM differ between states.
- There are differences from state to state with regard to which CAM treatments that can be provided by the authorized/licensed health care providers included in the **Directive 2005/36/EC(8).**
- Education and training programmes both for health professionals included in the **Directive 2005/36/EC(8)** and for other CAM providers differ from state to state. Consequently a medical doctor in one state could have some training in the CAM field included in the curriculum, while CAM training is not included in the curriculum in another state. Both curriculums are, however, accepted according to the professionals Directive.

Within the current legislation at the EU/EFTA level there is therefore room for a variety of CAM practice performed by authorized/licensed health care providers. This ranges from providers with no training in CAM practicing in a state where no, or only a select few, CAM modalities are permitted used by these providers, to, at the other extreme, providers practicing in states where there is considerable CAM training within the current curriculum, post-graduate accredited CME training courses in several CAM modalities, and authorization/licensing of CAM specialists in the respective professions.

This situation raises concerns with regard to the predictability, quality and safety of health care delivery to European citizens by licensed health care providers practicing CAM.

8.3.2 CAM provider without an authorization/license as a health care provider

Directive 2005/36/EC (8) on the recognition of professional qualifications influences the provision of CAM treatment in Europe also for those CAM providers who are not authorized/licensed as health care personnel. A few countries have established separate authorization/licensing for some categories of CAM providers (for example acupuncturists and chiropractors), and these are included in the professional groups regulated by Directive 2005/36/EC. These CAM providers can seek professional recognition within the countries that regulate them. Also CAM providers have a basic right to work in all European states under the **Directive 2004/38/EC[36] (4)** (Rights of Union citizens to move and reside freely).

[36] OJ L 158, 30.4.2004, p.77-123

However the individualised nature of member states' recognition of CAM professions means they cannot exercise this right across all member states. They can thus possibly be legally recognized in their own country, but not recognized in other EU or EFTA countries(21). With regard to what treatment they are allowed to give, and the provider and insurance regulations within private or public health systems, they are required to follow national legislation/regulations in each state. This severely hampers the free movement of both providers and patients even if the Cross-border Healthcare Directive and Social Security Regulation are in place.

Within the current legislation at the EU/EFTA level there is therefore room for a variety of CAM practice performed by providers who are not authorized/licensed health care providers. This ranges from an extreme of being refused to practise at all, because all treatment of people with health conditions is reserved for authorized/licensed health care providers only, to another extreme in some European countries where anyone can practise CAM without any CAM education or training. In a few countries fully trained providers are allowed to practise CAM with an authorization/license on equal terms to an authorized/licensed health care provider.

This extremely diverse situation raises, as in the case of authorized/licensed health care providers, concerns with regard to the predictability, quality and safety of CAM health care delivery to European citizens.

8.4 Obstacles

We have identified three obstacles that hinder the European Parliament Resolution call for "a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees".

The most important obstacle for this process is the Treaties of Rome and Lisbon clearly stating that the individual state has the responsibility for "the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them". This legitimizes and sustains the wide variations in CAM regulation across Europe.

The second obstacle is the unwillingness of individual European countries to voluntarily harmonize their legislation and regulation of CAM with other European states. If this had been done to a larger degree both patients and providers would be able to benefit from both "The right to move and reside freely" Directive, "The Professional Qualifications" Directive "The Cross-Border Healthcare Directive", as well as the Service and the Social security Directives.

The third obstacle identified is the unwillingness of some CAM organizations themselves to harmonize their self-regulation across Europe. A number of CAM disciplines have organized themselves at European level and established common professional platforms that have set

standards and procedures for voluntary self-regulation across Europe. But the lack of any legal backing at EU level and the lack of a requirement for CAM professionals to register with a professional association in many countries make it hard to firmly exert any common regulatory process across Europe.

Within the current European legal framework we think the second identified obstacle is the one where there is the largest window of opportunity. Sadly, this is also the obstacle with, in our view, the largest discrepancies.

9 Conclusions

The European Parliament Resolution on non-conventional medicine from 1997(11) stated that non-conventional medicine disciplines should be clearly identified and defined. The Resolution also calls on the Commission "to launch a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees".

In contrast to this, the EU treaties have repeatedly established that health policies are a national responsibility for the member states even if several EU Directives, Regulations and Resolutions influence how member states organize their national health policy and services.

The Cross-border healthcare Directive, in particular, respects the established differences in national healthcare systems. It aims to remove obstacles to the fundamental freedom that enable patients to choose to seek treatment across borders. This could potentially also include CAM treatment in countries where CAM treatment is included in the public health services. Regional collaboration between providers, purchasers and regulators from the different member states can ensure safe, high quality and efficient cross-border healthcare at a regional level. Historical and cultural similarities between neighbouring countries would thus seem to have the best chance to facilitate cross-border opportunities in the CAM area more than EU-wide Directives, Regulations and Decisions.

We think it is important to encourage individual states within culturally similar regions to voluntarily harmonize their CAM legislation and regulation. If this does not happen, and the EU sees such harmonization as valuable, it might need to reconsider its general respect for member states' health care organizational diversity.

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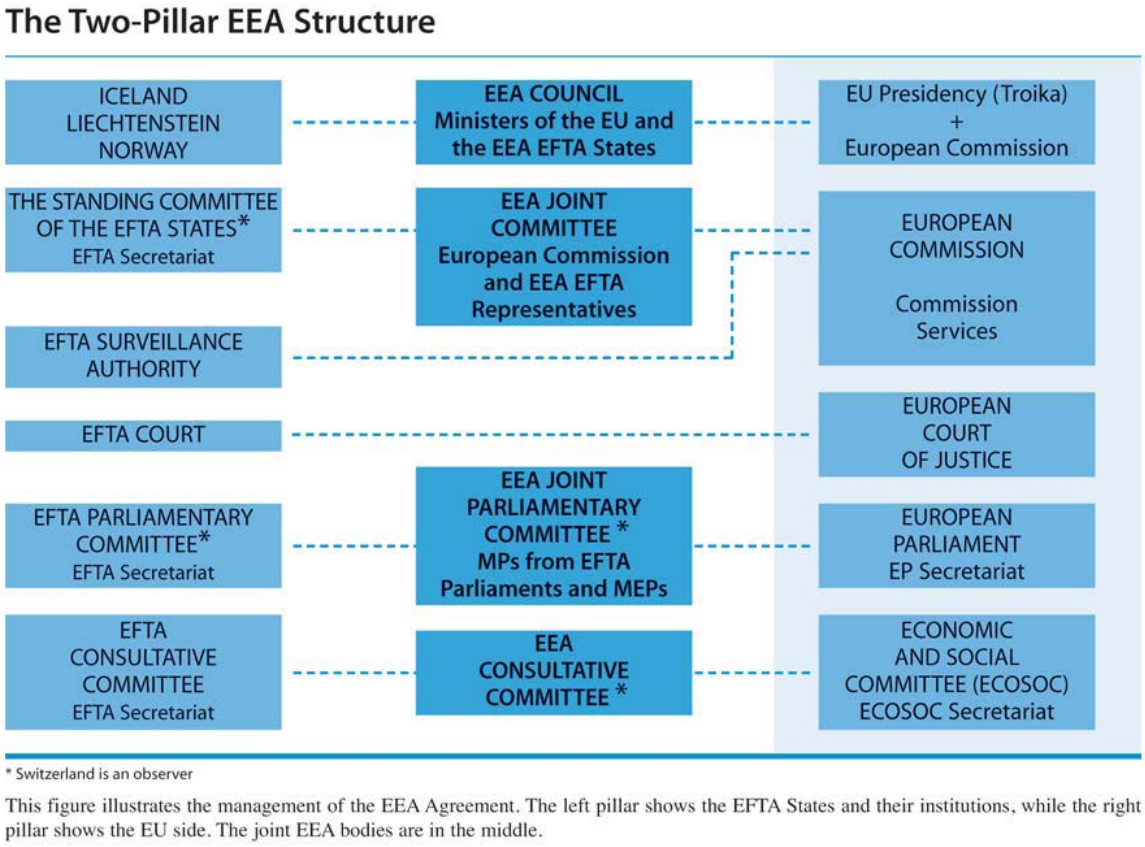
Attachment 1: The history of The European Economic Area (EEA)

- EFTA was established in 1960.
- EEC and EFTA - individual countries signed free trade agreements.
- **Original EFTA member states**: Austria, Finland, Iceland, Liechtenstein, Norway, Sweden, Switzerland.
- 6 December, 1992: Switzerland decided by a referendum not to join EEA – since then bilateral agreements have been established in certain areas.
- 1 January, 1994: The Treaty on a European Economic Area entered into force.
- 1 January, 1995: Austria, Finland and Sweden were included in EEA as EU member states.
- 1 May, 1995: Liechtenstein became a full participant in the EEA.
- 2004 and 2007: EEA expanded to include the twelve new member states joining the EU respectively in 2004 and 2007
- Free trade agreements are signed between EFTA/EEA and Turkey, Israel, Macedonia, Croatia, Albania and Serbia (among others).

European CAM associations:

ANME (Association of Natural Medicine in Europe)
CAMDOC Alliance (alliance of the four major European medical CAM umbrella organizations ECH, ECPM, ICMART and IVAA)
ECCH (European Central Council of Homeopaths)
ECH (European Committee for Homeopathy)
ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products (E.E.I.G.))
ECPM (European Council of Doctors for Plurality in Medicine)
EFCAM (European Forum for Complementary and Alternative Medicine)
EHTPA (European Herbal and Traditional Medicine Practitioners' Association)
EICCAM (European Information Centre for Complementary and Alternative Medicine)
ELIANT (European Alliance for Applied Anthroposophy)
EPHA (European Public Health Association)
ICMART (International Council of Medical Acupuncture and Related Techniques)
IVAA (International Federation of Anthroposophic Medical Association)
KB (Kneipp-Bund eV)

Attachment 2: The EEA structure



This figure illustrates the management of the EEA Agreement. The left pillar shows the EFTA States and their institutions, while the right pillar shows the EU side. The joint EEA bodies are in the middle.

Source: EFTA Fact sheet of the European free trade association - November 2007.

Attachment 3: Historical development of the right to move and reside freely

The states included in the CAMbrella project have developed their national legislation within this field according to their agreements with EU/EEA/EFTA. That means that every state's national legislation for health professionals and patients has to be investigated and compared to the EU legislation.

Below are some of the main documents showing the development in Europe:

Commission Regulation (EEC) NO 1251/70 of 29 June 1970[37](22)
on the right of workers to remain in the territory of a member state after having being employed in that state (no longer in force).

Family members who are not nationals of a member state exempt to the requirement to obtain an entry visa (**Council Regulation (EC) No 539/2001** of 15 March, 2001)[38](23).

Directive 2004/38/EC(8)[39] of the European Parliament and the Council of **29 April 2004**
on the right of citizens of the Union and their family members to move and reside freely within the territory of the member states **amending Regulation (EEC) No 1612/EC** and repealing Directives 64/221/EEC, 68/360/EEC 72/194/EEC 75/35/EEC 90/364/EEC and 93/96//EEC (text with EEA relevance).

The European Parliament Resolution of 15 November 2007 on application of Directive 2004/38/EC- P6_TA(2007)0534[40](24).

Decision of the EEA Joint Committee No 158/2007 of 7 December 2007[41](25) – amending Annex V (Free movement of workers) and Annex VIII (Right of establishment) to the EEA Agreement - Incorporation of the Directive 2004/38/EC.

Report from the EU commission. Brussels 10.12.2008[42](26)
from the Commission to the European Parliament and the Council on the application of **Directive 2004/38/EC** on the right of the Union and their family members to move and reside freely within the territory of the member states.

MEMO/09/311- Guidelines[43](27) on how to get the best out of Directive 2004/38/EC
Brussels, 2 July 2009.

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[37] OJ L 142, 30.6.1970, p. 24–26
[38] OJ L 81 21.3.2001, p.1
[39] OJ L 158, 30.4.2004, p. 77–123
[40] OJ L P6_TA(2007)0534 B6-0462 and 0464/2007
[41] OJ L 14, 20.1.1975, p. 14–14
[42] COM(2008) 725 final 10.12.2008
[43] MEMO/09/311 02/07/2009

Commission Report 10 December 2008 on the implementation of Directive 2004/38/EC(4).

Citizens from the member states that joined EU recently (see p.2.2.) enjoy unrestricted right of free movement. Transitional arrangements apply only to access to labour markets.

Directive should come into force by 30 April 2006. All the member states had in 2008 implemented the Directive text.

The Directive is incorporated in the EEA Agreement (EEA Joint Committee No 158/2007 of 7 December 2007), but the report writes that in 2008 the Directive 2004/38/EC was not adapted in the non-EU EEA countries Iceland, Liechtenstein, Norway.

The report mentions that the transposition of the Directive is incorrect. Cyprus, Greece, Finland Luxembourg Malta Portugal and Spain had in 2008 small problems of compliance. In other member states crucial provisions of the Directive had been incorrectly transposed.