



**Concerted Action for Complementary and Alternative
Medicine (CAM) Assessment in the Cancer Field**

CAM-CANCER Project

<http://www.cam-cancer.org>

**How are European patients safeguarded when using
complementary and alternative medicine (CAM)?**

**Jurisdiction, supervision and reimbursement status in
the EEA area (EU and EFTA) and Switzerland**

Dr G Ersdal on behalf of the CAM-CANCER Consortium



**CAM-CANCER project funded by the
European Commission within the 5th
Framework Program "Quality of Life"**



How are European patients safeguarded when using complementary and alternative medicine (CAM)?

Jurisdiction, supervision and reimbursement status in the EEA area (EU and EFTA) and Switzerland

Preface

The CAM-CANCER steering committee found a need to include a comprehensive overview of legal, reimbursement and supervisory issues in its presentation of CAM treatments in cancer. CAM-CANCER is an abbreviation for “Concerted Action for Complementary and Alternative Medicine Assessment in the Cancer Field”, and is funded by the European Commission’s 5th Framework Program. In the CAM-CANCER steering committee meeting of 29 March 2004, the partners agreed to allocate grants to experts in order to summarise and update the existing knowledge about the following issues:

Overview of legal issues in Europe. The idea is to review and summarise the legal status of CAM in European countries’ national laws.

Reimbursement of CAM by health insurances in Europe.

The Norwegian National Research Center in Complementary and Alternative Medicine (NAFKAM) in Tromsø was granted the project. During the fall of 2004 Susanne Ramstad, project assistant, made queries to the authorities in European countries concerning health laws and legislation of complementary and alternative treatments. Information has been collected from every country directly, and from written material about the matters. Since January 2005 Gerd Ersdal has been the leader of the project.

Gerd Ersdal is a physician with speciality in community health and has been the Medical County Officer of Troms County, Norway, for the last 8 years. To carry out this project she has had a leave of absence from her work as Medical County Officer.

The report describes the legislation, supervisory issues, and the reimbursement systems that the members in the EEA area (EU and EFTA) and Switzerland have adopted regulating complementary and alternative therapies.

Tromsø 28.10.2005

Gerd Ersdal
MD/Project Leader
NAFKAM University of Tromsø
9037 Tromsø
Norway

CONTENTS

1	Summary of the report	5
2	Introduction.....	6
2.1	Use of complementary and alternative treatment	6
2.2	Why regulate?	6
2.3	Recommendations by WHO and EU	7
2.4	Relation to earlier publications	8
3	Methods and materials	9
4	Overview of legal regulation of CAM, legal regulation of herbal products and reimbursement	10
4.1	Professionals and non-professionals, legal regulation.....	10
4.1.1	Who may treat sick people?	10
4.1.2	Who may provide CAM therapies?	11
4.1.3	Where is CAM legally regulated?.....	12
4.1.4	How health personnel are legally regulated?	14
4.1.5	How responsible professional conduct is defined and supervised?	14
4.1.6	How can CAM providers be “safe” without regulating them?	14
4.1.7	How patients are safeguarded when there is no regulation or registration?	15
4.2	Herbal products, legal regulation.....	15
4.3	Reimbursement, legal regulation	15
5	Regulation of medical practise - Safeguarding patients.....	15
5.1	Authorisation / licensing / protected title	15
5.2	Voluntary registration.....	16
5.3	Organisation of regulation	17
6	Regulation of herbal products – Safeguarding patients	18
6.1	Policy of the World Health Organization	18
6.2	Directives of European Union.....	19
7	Legal regulation in the EEA area (EU and EFTA) and Switzerland; professionals and non-professionals, reimbursement	20
7.1	Austria	20
7.1.1	Summary	20
7.1.2	Professionals and non-professionals	20
7.1.3	Reimbursement	21
7.2	Belgium.....	21
7.2.1	Summary	21
7.2.2	Professionals and non-professionals	21
7.2.3	Reimbursement	22
7.3	Cyprus	23
7.3.1	Summary.....	23
7.3.2	Professionals and non-professionals	23
7.3.3	Reimbursement	23
7.4	Czech Republic	23
7.4.1	Summary.....	23
7.4.2	Professionals and non-professionals	23
7.4.3	Reimbursement	23

7.5	Denmark.....	24
7.5.1	Summary	24
7.5.2	Professionals and non-professionals	24
7.5.3	Reimbursement	25
7.6	Estonia	25
7.6.1	Summary.....	25
7.6.2	Professionals and non-professionals	26
7.6.3	Reimbursement	26
7.7	Finland	26
7.7.1	Summary.....	26
7.7.2	Professionals and non-professionals	26
7.7.3	Reimbursement	27
7.8	France.....	27
7.8.1	Summary	27
7.8.2	Professionals and non-professionals	27
7.8.3	Reimbursement	29
7.9	Germany.....	29
7.9.1	Summary	29
7.9.2	Professionals and non-professionals	29
7.9.3	Reimbursement	30
7.10	Greece	30
7.10.1	Summary.....	30
7.10.2	Professionals and non-professionals	30
7.10.3	Reimbursement	31
7.11	Hungary.....	31
7.11.1	Summary	31
7.11.2	Professionals and non-professionals	31
7.11.3	Reimbursement	32
7.12	Iceland	32
7.12.1	Summary	32
7.12.2	Professionals and non-professionals	33
7.12.3	Reimbursement	34
7.13	Ireland	34
7.13.1	Summary.....	34
7.13.2	Professionals and non-professionals	34
7.13.3	Reimbursement	35
7.14	Italy	35
7.14.1	Summary.....	35
7.14.2	Professionals and non-professionals	35
7.14.3	Reimbursement	36
7.15	Latvia	36
7.15.1	Summary.....	36
7.15.2	Professionals and non-professionals	36
7.15.3	Reimbursement	37
7.16	Liechtenstein	37
7.16.1	Summary.....	37
7.16.2	Professionals and non-professionals	37
7.16.3	Reimbursement	38
7.17	Lithuania	38
7.17.1	Summary.....	38

7.17.2	Professionals and non-professionals	38
7.17.3	Reimbursement	38
7.18	Luxembourg	38
7.18.1	Summary.....	38
7.18.2	Professionals and non-professionals	38
7.18.3	Reimbursement	39
7.19	Malta	39
7.19.1	Summary.....	39
7.19.2	Professionals and non-professionals	39
7.19.3	Reimbursement	40
7.20	The Netherlands	40
7.20.1	Summary	40
7.20.2	Professionals and non-professionals	40
7.20.3	Reimbursement	41
7.21	Norway.....	41
7.21.1	Summary.....	41
7.21.2	Professionals and non-professionals	42
7.21.3	Reimbursement	43
7.22	Poland	44
7.22.1	Summary.....	44
7.22.2	Professionals and non-professionals	44
7.22.3	Reimbursement	44
7.23	Portugal	44
7.23.1	Summary.....	44
7.23.2	Professionals and no n-professionals	45
7.23.3	Reimbursement	45
7.24	Slovakia	45
7.24.1	Summary.....	45
7.24.2	Professionals and non-professionals	45
7.24.3	Reimbursement	45
7.25	Slovenia.....	46
7.25.1	Summary	46
7.25.2	Professionals and non-professionals	46
7.25.3	Reimbursement	47
7.26	Spain	47
7.26.1	Summary.....	47
7.26.2	Professionals and non-professionals	47
7.26.3	Reimbursement	48
7.27	Sweden	48
7.27.1	Summary.....	48
7.27.2	Professionals and non-professionals	48
7.27.3	Reimbursement	50
7.28	Switzerland	50
7.28.1	Summary.....	50
7.28.2	Professionals and non-professionals	50
7.28.3	Reimbursement	51
7.29	United Kingdom of Great Britain and Northern Ireland.....	51
7.29.1	Summary	51
7.29.2	Professionals and non-professionals	51
7.29.3	Reimbursement	53

1 Summary of the report

The use of the methods often characterized as complementary or alternative medicine is steadily growing among citizens of Europe. This development has been met with different legal approaches by the European countries. This report describes the legal regulation of complementary and alternative therapies in the EEA area (EU and EFTA) and Switzerland (29 countries).

Information about legal regulation has been collected from the Ministries of Health. Secondary literature, as well as documents published on the Internet has been used when complete primary data was unavailable. Each country has been described as completely as possible.

The report shows that in 19 out of 29 countries (Middle and Southern Europe) only regulated personnel may legally treat sick people while in the remaining 10 countries (Northern Europe) both regulated and non-regulated (anybody) may treat. In Middle and Southern Europe CAM, when provided within the public health service, is mostly practised by physicians. If practised outside the public health service it is administered by “consultants”. In Northern Europe anyone may offer CAM within the limits set by the monopolisation to qualified medical doctors of some medical procedures and the treatment of certain diseases.

Health authorities regulate CAM by offering authorisation, license, protected title or voluntary registration. Wide variations exist throughout Europe regarding the types of CAM that are legally regulated. Eighteen of twenty-nine countries regulate specific CAM therapies. In each country the supervising body (health authorities or medical federations), defines which type of CAM is considered “responsible professional conduct” when provided by regulated personnel. In some countries the practise of CAM by regulated personnel is severely restricted, while in other countries regulated personnel may perform CAM quite freely.

EU directives regulate herbal products in the European countries, and these directives are being implemented in national legislation. This report does not present the national legislation work carried out as a follow up of the EU directives.

A major challenge for the authorities in all countries is to what degree and in what way patients attending “consultants” of CAM (Middle and Southern Europe) and non-regulated CAM providers (Northern Europe) can be adequately and legally safeguarded. An additional challenge is to agree on the efficacy and quality of CAM, and consequently determine the therapies to be offered as a regulated health service.

2 Introduction

2.1 Use of complementary and alternative treatment

Patients and health personnel show a growing interest in exploring complementary and alternative medicine (CAM)¹. The use of CAM in the European countries, where data is available, shows that 20% to 70% of the population has experienced CAM at some point during their lifetime². The exact frequency of the use of these methods by cancer patients is difficult to evaluate due to the heterogeneity of approaches and variety of methods, with some being used as complementary treatments to conventional ones and others as curative treatment³. The most commonly used CAM therapies in Europe are homeopathy, phytotherapy, anthroposophic medicine, naturopathy, Traditional Chinese Medicine (including acupuncture), osteopathy and chiropractics⁴. The popularity of the individual therapies, however, differs widely between countries.

CAM is primarily provided by physicians in Middle and Southern Europe, while in Northern Europe treatment providers outside of the established health service constitute the core CAM providers. In some countries the practise of CAM outside of regulated health care is illegal and violations are considered an offence (Middle and Southern Europe). In other countries (Northern Europe) anybody may provide CAM within the limits set out by the monopolisation to established health care of some medical procedures and treatment of certain diseases.

The use of herbal products constitutes a substantial part of the increase in CAM use, and the international trade in this market is growing. Countries face major challenges in the development and implementation of the regulation of herbal products⁵. These challenges are related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring and lack of knowledge about CAM within national drug regulatory authorities⁶.

2.2 Why regulate?

In most European countries the authorities' justification for regulation of complementary and alternative medicine (CAM) is to protect the population with regard to harmful herbal products and incapable and unqualified treatment providers. At the same time, many European countries have the basic political intent to give patients the freedom of choice concerning herbal products and CAM therapies.

Federations of CAM treatment providers are, in many countries, working for statutory regulation of their therapy, thinking this will further advance the interest of CAM. A

¹ National policy on traditional medicine and regulation of herbal medicines: Report of a WHO global survey. Geneva: World Health Organisation, May 2005.

² Johannessen H. Alternativ behandling i Europa. Århus: Viden- og forskningscenter for alternativ medicin. Mars 1995, revised Mai 2001.

³ Schraub S. Unproven methods in cancer: a worldwide problem. Support Care Cancer 2000; 8: 10-15.

⁴ WHO global atlas of traditional, complementary and alternative medicine. Kobe, Japan: World Health Organisation, the WHO Centre of Health Development, 2005.

⁵ National policy on traditional medicine and regulation of herbal medicines: Report of a WHO global survey. Geneva: World Health Organisation, May 2005.

⁶ Ibid

number of the more well established CAM therapies are already statutorily regulated in many countries. Other supporters of CAM therapies have the opinion that statutory regulation will potentially “colonise” CAM by established health care personnel. A system of ethics-led regulation has been proposed, which is responsive to the holistic dimension of CAM, and which promotes and enhances patient-centred values, which are so much at the heart of holistic therapies⁷.

2.3 Recommendations by WHO and EU

The WHO Traditional Medicines Strategy 2002-2005 outlines the role and activities in traditional medicines / complementary and alternative medicine (TM/CAM)⁸. The strategy incorporates four objectives, two of which focus on safety:

1. Policy – Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes.
2. Safety, efficacy and quality – Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge-base on TM/CAM, and by providing guidance on regulatory and quality assurance standards.

The European Union (EU) treaty came into force on November 1 1993. The treaty was intended to open a large market zone without borders, enabling the free movement of persons, goods, services, and capital. The treaty’s regulation of movement of persons and goods affects in particular health service and medications. WHO gives the following description in the “Legal status of TM/CAM: A worldwide review”

Although the free movement of persons within the European Union is the cornerstone of the Treaty of Rome, the diversity of national policies severely limits its applicability to practitioners of CAM. Case 61/89 of the European Court of Justice involved an acupuncturist without allopathic medical qualifications practising in France. The courts decision confirmed the right of individual countries to make their own legislation on whether or not to reserve the practice of medicine to allopathic doctors.

Nonetheless, in April 1994, European Deputy Paul Lannoye presented a proposal on the status of CAM to the European Parliament Committee on the Environment, Public Health, and Consumers Protection. He asked for provisions for CAM within social security systems, the incorporation of CAM into the European Pharmacopoeia, an end to prosecutions of non-allopathic practitioners in the countries where the practise of medicine is the exclusive domain of allopathic providers, and a pan-European system of recognition and regulation of CAM practitioners along the lines of the British Osteopath and Chiropractor Acts. He also requested a research budget of 10 million Euros per year for five years. At the last moment the European Parliament cancelled the vote on the proposal.⁹

In May 1997 The European Parliament adopted a resolution on the status of non-conventional medicine¹⁰. The resolution called the Commission to:

1. Launch a process of recognising non-conventional medicine.
2. Carry out a thorough study into safety, effectiveness, area of application and the complementary or alternative nature of all non-conventional medicines with a view to their eventual legal recognition....
3. Draw up a comparative study of the various national legal models to which non-conventional medical practitioners are subject....

⁷ Stone J, Matthews J. *Complementary medicine and the Law*. Oxford University Press 1996.

⁸ WHO, *Traditional Medicine Strategy 2002-2005* (document WHO/EDM/TRM/2002.1). Geneva: World Health Organization, 2002.

⁹ *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review*, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001: s 188.

¹⁰ European Parliament, Resolution A4 1997/0075.

4. In formulating European legislation ... make clear distinction between non-conventional medicines that are “complementary” in nature and those which are “alternative” medicines in the sense that they replace conventional medicine...

A resolution of the European Parliament, however, is not a binding act, but a declaration of policy. Nonetheless, the adoption of the resolution has led several countries to consider revising legislation¹¹.

Concerning CAM providers and CAM therapies, an EU resolution in 1999 stated:

“In the health field, it is important to preserve the diversity of national legislation and practise that is one of Europe’s assets: people’s attachment to their own systems and tradition must not be called into question. Nevertheless, the Assembly believes that a common European approach to non-conventional medicine based on the principle of patients’ freedom of choice in health care should not be ruled out.”.....“The Assembly believes that the best guarantee for patients lies in a properly trained profession, which is aware of its limitations, has a system of ethics and self-regulation and is also subject to outside control.”¹²

This resolution and case 61/89 of the European Court of Justice gave the members of the European Union the opportunity to regulate CAM therapies and providers according to health legislation and CAM tradition in their own countries.

The EU parliament has, since 1994, adopted several directives regulating the trade of herbal products. Two directives concerning homeopathy came into force on January 1994: one applicable for homeopathic products for humans and one applicable for homeopathic veterinary products. The directive on traditional herbal medical products will be in force from 1 November 2005 (2004/24/EC), and the directive on food supplements was set in force from 1 August 2005 (Vitamins & Minerals, 2002/46/EC). These directives will be adopted in the legislation of the European countries and will thus harmonize the regulation of herbal products and food supplements.

2.4 Relation to earlier publications

In 1985 Stephan¹³ categorised different legislative approaches to regulate medical practise. He distinguished four systems; the monopolistic system, the tolerant system, the inclusive system and the integrated system. In Europe, only the monopolistic and tolerant systems are represented according to his categorization. In the monopolistic system only the practise of “scientific” medicine by authorised professionals is recognised as legal to the exclusion of, and sanctions against, all other forms of care. In the tolerant system only the practise of scientific medicine is regulated, while the practise of various forms of CAM is to some extent tolerated by law. These two systems can, however, overlap. In 1997 De Bijl and Nederveen-Van de Kragt¹⁴ introduced a new category called the mixed system. In this system only health care professionals are allowed to perform specific medical procedures and treat some serious diseases, and the violation of this limited monopoly results in an offence. For the remaining medical practises, there are no such restrictions.

¹¹ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

¹² European Parliament Resolution 1999/1206

¹³ Stephan J. Traditional and alternative System of Medicines: A Comparative Review of Legislation. International Digest of health Legislation, 1985, Vol. 36, No. 2.

¹⁴ De Bijl N, Nederveen - Van de Kragt I. Legal safeguards against medical practise by not suitable qualified persons. European journal of health Law 1997; 4: 5-18.

In his book, “The Legal Status of Complementary and Alternative Medicine in Europe” (1999), Stefano Maddalena concludes (s 292):

“A trend is starting in Europe to integrate some alternative medicine into health care systems. A few countries have already passed the first step in the process of integrating complementary medicine, which is the recognition of their usefulness and perhaps even their necessity. Indeed, some countries do not only tolerate alternative practitioners, but they have built complete systems of education and examination for them. Some governments also either begin to include some reimbursement for complementary medicines in their social insurance schemes, or unofficially tolerate that some alternative treatments are being covered by public funds. At the same time, many private insurance companies propose policies including coverage for complementary medicine”.¹⁵

In 2001 the World Health Organization published a summary called “Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review”¹⁶, and in 2005 a “Global Atlas of Traditional, Complementary and Alternative Medicine”¹⁷. The reviews show that national recognition and regulation of traditional and complementary/alternative medicine varies considerably.

3 Methods and materials

In the fall of 2004 the health ministries in 29 European countries were contacted, by telephone or e-mail, to collect documentation on the regulation of health services, health personnel, CAM practitioners, CAM products and supervisory practises. The information was collected by means of a written questionnaire (e-mail) or by a similarly structured interview guide (telephone). The choice of a telephone interview was made when an e-mail address was either unavailable or when no response was received to the e-mail. All countries except France, Italy, Latvia, Liechtenstein, Portugal and Slovakia replied to our email or phone call, some after several reminders. Where primary data was limited, secondary literature, as well as documents published on the Internet has been used. In April 2005 the first author (GE) met with the responsible persons for this area in the health departments of The Netherlands, Austria, Hungary and Slovenia¹⁸. The purpose of these site visits was to obtain detailed information of how the legal and regulatory framework was put into practise in four countries representing different approaches to CAM regulation.

A draft of the final report, based on the information obtained from each country, was sent by e-mail in May / June 2005 asking every country to double-check the information presented about own country. Nineteen countries submitted comments regarding the description, updated information was received from six countries, but Cyprus, France, Latvia and Portugal gave little or no feedback.

¹⁵ Maddalena S. The legal status of complementary medicines in Europe. Berne: Universitè de Neuchâtel, Stämpfli Publisher Ltd. 1999.

¹⁶ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

¹⁷ WHO global atlas of traditional, complementary and alternative medicine. Kobe, Japan: World Health Organisation, the WHO Centre of Health Development, 2005.

¹⁸ Den Haag 26 April 2005, Wien 28 April 2005, Budapest 29 April 2005 and Lublijana 2 Mai 2005

Two systems are proposed in this report for understanding the differences in legal regulation of who may treat sick people in Europe: The “all-regulated system” and the “semi-regulated system”. Some countries have regulations that do not make it crystal clear to which system they belong.

EU directives regulating the trade of herbal products are being incorporated into the national legislation of every European country. The result is a harmonization of the regulation of herbal products, and this report will not cover the legal regulation of this field in each country.

In this report the terms “complimentary / alternative / non-conventional medicine” (CAM) refers to a broad set of health practises that are not in most European countries part of the country’s own tradition and are not integrated into the dominant health care system¹⁹. The term “CAM provider” is used in this report as an abbreviation for alternative treatment practitioners who are not regulated health care personnel. The term “European countries” as used in this report is defined as countries in the EEA area (EU and EFTA) and Switzerland. The expression “who may treat” is used as an abbreviation for “who may provide medical acts”.

4 Overview of legal regulation of CAM, legal regulation of herbal products and reimbursement

This report gives a detailed description of:

1. The legal regulation of professionals and non-professionals practising CAM (chapter 5 and 7)
2. The legal regulation of herbal products (chapter 6)
3. Reimbursement of CAM (chapter 7)

The following gives a summary of those chapters.

4.1 Professionals and non-professionals, legal regulation

4.1.1 Who may treat sick people?

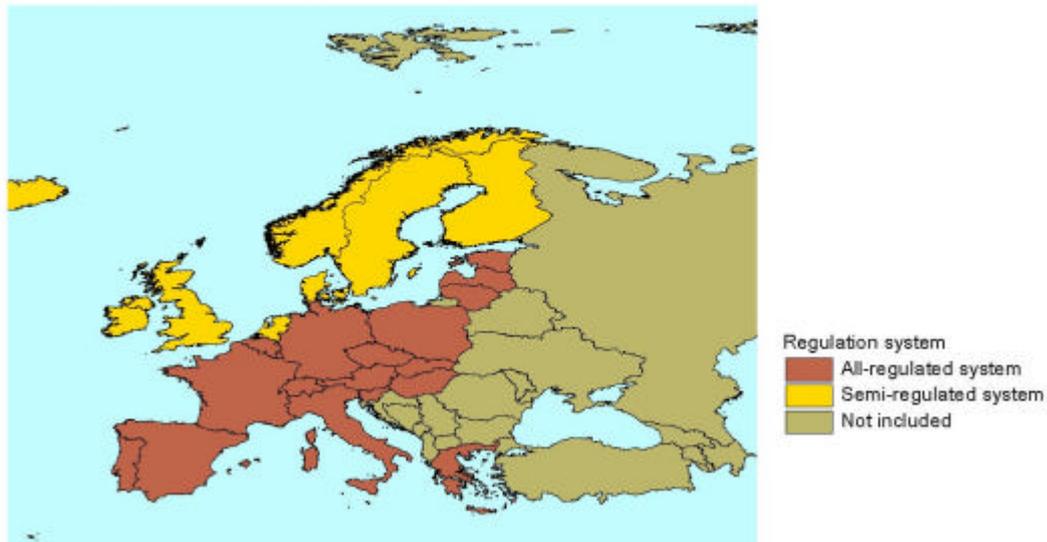
European countries differ substantially with regard to how they regulate treatment-related activity. In 19 countries only personnel who are regulated (authorised, licensed or given a protected title) can legally perform treatment-related activity. In the following these countries are referred to as having an “all-regulated system”. In the remaining 10 countries anyone can perform treatment-related activity, limited only by certain restrictions with regard to which conditions can be treated, and the procedures to be utilized. In this report these countries are referred to as countries with a “semi-regulated system”. That means that anybody in these countries may perform safe medical procedures, treat non-serious diseases and provide preventive/prophylaxis. (Table 1)

¹⁹ WHO, Traditional Medicine Strategy 2002-2005 (document WHO/EDM/TRM/2002.1). Geneva: World Health Organization, 2002.

Table 1: Countries where only authorised / licensed personnel may treat (all-regulated) and countries where anybody may treat but with some restrictions (semi-regulated)

	“All-regulated system” n=19	“Semi-regulated system“ n=10	
Countries	Austria, Belgium, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Latvia, Lithuania, Luxembourg, Italy, Poland, Portugal Spain, Slovenia, Slovakia?, Switzerland,	Denmark, Finland, Iceland, Liechtenstein, Ireland, Malta, The Netherlands, Norway, Sweden, UK	
Who may treat	Regulated personnel	Regulated personnel	Anyone
Health related activity they may perform:	-“risky” medical procedures -treating serious diseases -safe medical procedures -preventive/prophylaxis	-“risky” medical procedures -treating serious diseases -safe medical procedures -preventive/prophylaxis	-safe medical procedures -preventive/prophylaxis

Regulation systems in Europe



4.1.2 Who may provide CAM therapies?

Patients in countries with an “all-regulated system” may be offered CAM treatment by regulated personnel (often physicians), but may also in some of these countries be offered CAM by non-regulated CAM providers calling themselves “health consultants”. This activity is legal as long as the CAM providers define themselves as counsellors of “healthy life style”, and do not present themselves as health personnel (e.g. Estonia, France, Greece, Slovenia and Spain). In these countries, health service is specifically defined, and non-regulated providers may, in some of the countries, be prosecuted if providing services that may be considered as health services (e.g. Luxembourg). In

other countries, non-regulated providers (often labelled as “intruders”) may perform treatment-related activity without being prosecuted although it is officially illegal (e.g. Italy, Latvia, Switzerland).

Inhabitants in countries with a ”semi-regulated system” may be offered CAM treatment provided by either regulated personnel or by non-regulated or registered CAM providers. Non-regulated or registered providers offer most of the given CAM treatments in these countries²⁰. In these countries non-regulated providers can be prosecuted only if they perform medical procedures that are legally restricted to regulated personnel.

4.1.3 Where is CAM legally regulated?

The extent to which countries have established a legal regulation of CAM and how such regulation is performed varies widely. Some countries have laws regulating CAM in general, some regulate specific CAM therapies, while still others have no CAM legislation at all (table 2). All countries without any CAM legislation except for the Netherlands, have an “all-regulated system”.

Table 2: Legislation of CAM in European countries

LEGISLATION	NUMBER	COUNTRY
CAM legislation	7	Belgium (1999), Denmark (2004), Germany (1939)*, Hungary (1997), Iceland (2005), Norway (2004), Portugal (2003)
CAM legislation in preparation	5	Ireland, Luxembourg, Poland, Slovenia, Sweden
Legislation of some CAM therapies **	9	Czech Republic, Cyprus, Finland, Italy, Lithuania, Latvia, Liechtenstein, Malta, UK Great Britain
No CAM legislation	8	Austria, Estonia, France, Greece, The Netherlands, Spain, Slovakia, Switzerland***

* Regulation of Heilpraktiker

** See table 3

*** No national legislation in Switzerland, but cantons have legislation of some therapies

Table 3 shows details of the regulation of specific CAM therapies adopted by the European countries. To our knowledge 2/3 of the countries have some kind of regulation²¹. What type of CAM therapies that are regulated differs between countries, but the most commonly regulated are acupuncture, chiropractics and homeopathy. In some countries specific CAM therapies are defined as medical specialities (Not shown in the table).

²⁰ Johannessen H. Alternativ behandling i Europa. Århus: Viden- og forskningscenter for alternativ medicin. Mars 1995, revised Mai 2001.

²¹ Some information may be missing due to some countries missing response

Table 3: Specific CAM regulated providers in European countries by year of legislation

X: Year of legislation is unknown

Y: New law is in preparation

Countries	Regulating CAM providers by law								License	CAM Register*	
	No	Yes	Chiro- practics	Osteo- pathy	Napra- pathy	Homeo- pathy	Acu- puncture	Naturo- -pathy			Phyto- therapy
Austria	no										
Belgium		1999	1999			1999	1999				
Cyprus		x	y				y				
Czech Republic						2002					
Estonia	no										
France	no										
Denmark		1992									2004
Finland		1994	1993	1994							
France			2002								
Germany **										1939	
Greece	no										
Hungary***										1997	
Iceland		1990	2005								2005
Ireland	no										y
Italy		x									
Latvia (physicians)****						x	x				
Liechtenstein		1985									
Lithuania (physicians)****						x					
Luxembourg	no										
Malta		x	x				x				
The Netherlands	no										
Norway		1988									2004
Poland	no										
Portugal		2003	2003			2003	2003	2003	x		
Spain	no										
Slovakia ?	no										
Slovenia	no										
Sweden		1989		1994							y
Switzerland*****		x	x							x	
UK		1994	1993			1950	y		y		x
Number	11	13	8	2	6	4	1	1	3	4	

* The countries are offering voluntary registration schemes for CAM providers

** Germany is licensing Heilpraktikers who may provide CAM

*** Hungary is licensing CAM physicians and CAM practitioners

**** Physicians with a certificate from the university

***** In Switzerland chiropractics has been regulated by the cantons for many years. The government is planning a national regulation of Chiropractiss in the near future. Osteopaths are regulated in 8 cantons. In 11 of the cantons, license is given Heilpraktikers as in Germany.

4.1.4 How are health personnel legally regulated?

All the European countries have similar systems of safeguarding patients undergoing treatment-related activity. Personnel are governmentally regulated and given an authorisation / license / protected title if they fulfil specific qualifications. These privileges may be given to physicians, nurses, midwives, dentists, pharmacists and various other personnel groups. Specific CAM providers are likewise authorised or licensed in 2/3 of the European countries (table 3), but some countries limit the regulation to only a protected title (e.g. England, Finland). A few countries regulate health personnel who want to practise CAM. In Belgium, Hungary, Latvia, and Portugal health personnel are authorised/ licensed or given a certificate if they want to practise CAM. Regulated personnel are supervised either by the authorities or if delegated, by medical federations. Professionals may lose their authorisation / license / title if the condition for authorisation / license / title is seriously violated. This system gives patients protection against incapable practitioners.

4.1.5 How responsible professional conduct is defined and supervised?

Health legislation and federation-specific ethical rules of conduct regulate the work of regulated personnel (professionals), while supervising bodies control their work. To safeguard patients' rights according to "responsible professional conduct", duty of confidentiality, duty of documentation, ethical rules, rules for insurance and marketing have been put in place.

The supervising bodies in European countries differ substantially in how they relate CAM to "responsible professional conduct" of regulated personnel. In the Czech Republic, Luxembourg, Slovenia, Spain and Sweden, for example, only a minor part of CAM treatments are regarded as "responsible professional conduct", while in Estonia, Germany, Hungary, Italy, and Poland, most CAM treatments are regarded as "responsible professional conduct". In the other countries some CAM, most often acupuncture, chiropractics, osteopathy or homeopathy are regarded as "responsible professional conduct". If regulated personnel practise CAM, the treatment must, of course, be considered as "responsible professional conduct" by the supervising body in that country. If this body finds the treatment not to be "responsible professional conduct", the individuals' authorisation / license / title may be retracted.

In some countries the authorities have delegated the regulation, registration and supervising authority to the medical federations. In countries with an "all-regulated system" (e.g. Austria, France, Italy, Slovenia, and Spain), the medical federations are thus given the authority of defining which CAM treatments can be made available to the public.

4.1.6 How can CAM providers be "safe" without regulating them?

In countries with a semi-regulated system", some governments (e.g. Denmark, Iceland, Norway, UK) offer a voluntary registration scheme for CAM providers. The purpose of the registration is to safeguard and ensure the rights of consumers who seek "registered" CAM providers. A "registered" CAM provider must have a membership in a government-approved providers' federation. For a federation to be approved educational qualifications, certain ethical rules, rules for responsible professional conduct, rules for

confidentiality as well as procedures for documentation are most often required. Which requirement the authority makes when approving a federation determines the safeguarding of a consumer.

4.1.7 How patients are safeguarded when there is no regulation or registration?

Both registered personnel and CAM providers, whether legally regulated, registered or not, are all subject to civil and criminal laws which act as a framework for every individual and organisation in every European country. In every country the penal code may be applied.

4.2 Herbal products, legal regulation

The EU directives regulating the trade of herbal products are currently being incorporated into the national legislation of the European countries. The challenge for the countries is to implement similar legislation, thereby avoiding differences in the regulation of herbal products.

4.3 Reimbursement, legal regulation

The National Health Insurance systems in most European countries do not reimburse CAM treatment, but there are a few exceptions, mostly when physicians have prescribed the treatment. There are private insurance systems in a number of the countries that more or less cover CAM treatment. Most of them, similar to the national health insurance systems, only do this when physicians have prescribed the treatment.

5 Regulation of medical practise - Safeguarding patients

Every European country regulates by law the access to medical practise and the use of titles. Practitioners are authorised / licensed / given a protected title and the quality of the service is controlled by supervisory bodies. Some countries offer, in addition, a voluntary registration scheme for CAM providers.

5.1 Authorisation / licensing / protected title

Authorising or licensing (in some countries) practitioners within a certain profession allows governments to secure the quality of a given service. An authorisation is given when the practitioner can provide educational and other qualifications. Authorisation is

granted in the health care service to practitioners, such as physicians, nurses, midwives, and dentists, giving them the right to use a specific title, in addition to accepting various privileges and responsibilities. The governments decide which professions are authorised / licensed. Some European countries authorise CAM practitioners as health personnel. Some countries' statutory regulations recognise the use of a title but do not thereby automatically authorise the practitioner the status of health personnel

Health acts and ethical rules of the practitioners' own federations regulate the work of authorised / licensed personnel. The common objective is to contribute to safety of the patients and to a high quality of health service, as well as to maintain confidence in health personnel and services. The most important aspects of safeguarding the patients are requirements regarding responsible professional conduct, duty of confidentiality, obligatory documentation, ethical rules, regulations about insurance and rules concerning marketing.

Regulated personnel are supervised. The supervisory body controls the quality of the work administered by the personnel and monitors adherence to laws and regulations. The personnel may lose their authorisation if the law is violated. If the violation is serious, the supervisory body may ask the police to investigate the matter.

5.2 Voluntary registration

In some countries where anybody is allowed to treat ("semi-regulated system"), the government provides a voluntary registration scheme for CAM providers. The registration task may be accomplished by the authorities or by the federations. The intent of the regulation is to safeguard the patient and ensure the rights of consumers who seek "registered" CAM providers.

To be a "registered CAM provider" the provider must, in all countries, have a membership in a practitioners' organisation approved by the government. Special characteristics are required for a federation to be approved. Typically the federations must have membership requirements concerning educational qualifications, ethical rules, claim of responsible professional conduct, of confidentiality, and documentation routines. Furthermore, the organisation must establish a commission for complaints. The ethical issues that "approved federations" regard as relevant for all CAM providers are competence, research, respect for autonomy and consent, special duties towards children, respect of confidentiality, maintenance of professional boundaries, professional etiquette, and presence of effective complaint mechanisms²².

The health authorities do not undertake supervision of the practise of registered CAM providers. If CAM providers are registered, violation of the rules of the federation may exclude the person from membership of the federation. The CAM provider will thereby lose his/her "registration". If CAM providers violate current legal rules, however, the authorities (often the health authorities) or patients can ask the police to investigate the matter. The only existing public supervision of the field is the marketing control by the Consumers' Ombudsman. The safeguarding of consumers seeking "registered" CAM providers depends on the governments' requirements when approving a federation.

²² Stone J. Ethical issues in complementary and alternative medicines. *Complementary Therapies in medicines* 2000; 8, 207-213.

5.3 Organisation of regulation²³

There are three main models used to regulate the practise of medicine:

1. Direct Government-administered regulation
2. Government-sanctioned self-regulation
3. Independent self-regulation

These three approaches differ in the depth of direct government involvement. These systems are, of course, often used in tandem with other acts, which may regulate certain aspects of the health service and medical practise.

Direct government-administered regulation

In most European countries the government authorises, registers and supervises the personnel. The authorities can withdraw the authorisation of health personnel if the law is violated. If the violation is serious, the authorities may also ask the police to investigate the matter. This implies that the government through the appropriate authorities decides to what extent the use of CAM by regulated personnel can be designated as “responsible professional conduct”.

Government-sanctioned self-regulation

In some countries the law delegates the tasks of authorisation, registration and supervision of practitioners to the medical federations. If the rules are violated, the federation may withdraw the authorisation and may ask the police to investigate the matter. This implies that the medical federations decide to what extent the use of CAM by authorised personnel can be designated as “responsible professional conduct”.

Independent self-regulation

Some federations of CAM providers are developing what they call “self-regulation”. “Self-regulation” is a process in which federations of individual therapies develop their own statistics, educational programmes, code of ethics, research programmes and standards of competence²⁴. In some countries, self-regulation is required for a federation to be approved by the government.

²³ Referee for the chapter where nothing else is noted:

Stone J, Matthews J. Complementary medicine and the Law. Oxford University Press 1996.

²⁴ European Council for Classical Homeopathy. Report: The Recognition and Regulation of the Practise of Homeopathy in Europe, June 2004.

6 Regulation of herbal products – Safeguarding patients ²⁵

During the past few decades, public interest in CAM has increased considerably in the industrialized countries. Medical plants and herbal medicines make up an essential part of this increase, and international trade with herbal medicines and other kinds of traditional preparations is growing. Although leading to new treatment possibilities, the commercial trade of these products represents a considerable challenge for governments to ensure safety, efficacy and quality for the users.

Herbal products are regulated as medicine or as food (food supplements and cosmetics). Claims of effect can only be made if the product is regulated as medicine. Countries classify medicinal plants or herbs, or products derived from them, differently with regard to being food or medicine, and have various approaches to licensing, dispensing, manufacturing, and trading to ensure that their safety, efficacy and quality standards have been adopted. The legal situation regarding herbal preparations has, until recently, varied considerably from country to country.

6.1 Policy of the World Health Organization

The World Health Organization stated the policy of traditional medicine in 1991 as follows:

“WHO collaborated with its Member States in the review of national policies, legislation and decisions on the nature and extent on the use of traditional medicine in their health systems”.

The major objectives of the Traditional Medicine Programme in WHO were to facilitate the integration of traditional medicine into national health care systems, to promote the rational use of traditional medicine through the development of technical guidelines and international standards in the field of herbal medicine and acupuncture, and to act as a clearing house for the dissemination of information on various forms of traditional medicine. “Guidelines for the Assessment of Herbal Medicines” were adopted by WHO in Ottawa in 1991. These guidelines define basic criteria for the evaluation of safety, efficacy and quality of herbal medicines to assist national regulatory authorities, scientific organizations, and manufactures.

The World Health Assembly adopted in May 2003 resolution WHA56.31 on traditional medicine. The resolution requested WHO to support Member States by providing internationally acceptable guidelines and technical standards and also evidence-based information to assist Member States in formulating policy and regulations to control the safety, efficacy and quality of traditional medicines²⁶.

WHO has made a major effort in the area of herbal medicine.

²⁵ Referee for the chapter where nothing else is noted:

Regulatory Situation of Herbal Medicines: A Worldwide Review (document WHO/TRM/98.1). Geneva: World Health Organisation 1998.

²⁶ National policy on traditional medicine and regulation of herbal medicines: Report of a WHO global survey. Geneva: World Health Organisation, May 2005: side 6.

6.2 Directives of the European Union

The EU has developed a comprehensive network to facilitate the free movement of goods. According to Directives 1965/65/EEC and 1975/318/EEC, pharmaceutical products require pre-marketing approval before gaining access to the market. Requirements for the documentation of quality, safety, and efficacy, and the dossier and expert reports are laid down in Directive 1991/507/EEC.

In order to achieve free movement of medicines within the common market of the European Union and a centralized system of marketing authorisation (e.g. for new chemical entities) with the possibility of application at a national level, a system of mutual recognition of marketing authorisation decisions have been installed (Directive 1993/39/EC). This “decentralized procedure” provides as a general rule that an assessment by one national authority should be sufficient for subsequent registration in other Member States. The Directive 1993/39/EC has been binding since 1995.

The EU parliament has, since 1994, adopted several directives regulating the trade of herbal products. Two European directives on homeopathy came into force on 1 January 1994, one applicable for homeopathic products for humans and one applicable for homeopathic veterinary products. The purpose of the directives is to ensure a common European market for these products. The provisions regulate manufacturing, inspection, marketing and labelling. An important rule is the establishment of a simplified registration procedure applying to medicines containing less than one part per 10 000 of the undiluted tincture or less than 1/100th of the smallest dose used in established medicine.

The European Union passed a new directive in 2004 regarding traditional herbal medicinal products (2004/24/EU). The aim of this directive is to guarantee a high level of health protection for European patients by giving them access to medicines of their choice, provided all the necessary safeguards are met. This will also ensure a single market for traditional herbal medicines by introducing similar rules and procedures, thereby encouraging cross-border trade for these products. The new legislation introduces a simplified system for registration of traditional herbal medicinal products in the European Union Member States. According to the directive, herbal preparations are to meet the same quality requirements as all registered medicinal products (“officially approved medicine”). However, to avoid unnecessary testing, the legislation states that clinical trials will not be necessary when sufficient knowledge already exists about a particular product. Medicines may be given a marketing authorisation without proof of efficacy, provided they

1. are safe,
2. have been in traditional medical use throughout a period of at least 30 years preceding the date of application. At least 15 of the 30 years must relate to the European Union,
3. are produced to expensive standards that are more appropriate to pharmaceutical drugs than to naturally occurring substances.

The directive requires all Member States to comply by 30 October 2005. CAM users in many European countries are worried that with this regulation, some herbal medicines will not be available after 1 November 2005.

In 2002 the European Union passed a directive concerning food supplements (Vitamins & Minerals 2002/46 EC). According to this directive the Member States shall ensure that food supplements may be marketed within the community only if they comply with

the rules laid down by the directive. The directive has two annexes that list the vitamins and minerals that may be used in the manufacturing of food supplements. Nutrients that are not on the “Positive list” cannot be used. The directive allowed for a derogation period so that nutrients not listed in the annexes could continue to be used through July 2005 but prohibit the trade of products that do not comply with the directive from 1 August 2005 at the latest. Many of the vitamins and minerals used by CAM providers in some countries are not on the “Positive list” and cannot be marketed after 1 August 2005.

These directives have to be adopted in the legislation of the European countries and will thus harmonize the regulation of herbal products and food supplements

7 Legal regulation in the EEA area (EU and EFTA) and Switzerland; professionals and non-professionals, reimbursement

7.1 Austria

7.1.1 Summary ²⁷

In Austria treatment is restricted to legally regulated personnel. CAM is not regulated.

7.1.2 Professionals and non-professionals

Legally regulated personnel

According to the Law of Physicians (1998) and laws regulating other health professions, only authorised medical professionals are allowed to carry out medical acts. According to the Federal Medical Law the acts of medicine include all activities based on medico-scientific knowledge carried out directly on human beings performed for the purpose of diagnosis, treatment, prophylaxis, etc. According to this law, only physicians may treat. Special laws may give permission to other professions to practise specific types of medicine.

According to the law only methods, which are scientifically recognised, and methods with experienced medical effects may be provided. The Expert Medical Board has advised the Ministry of Health that acupuncture and neuraltherapy may be practised. However, physicians are allowed to use medical techniques as they desire, provided being responsible professional conduct and in an agreement with their patients. There are no legal regulations of CAM in the country.

²⁷ Reference for the chapter where nothing else is noted:

Federal Ministry of Health and Women, Meeting in Vienna 28.04.05 (<http://www.bmgf.gv.at>)

Supervising regulated personnel

According to the Law of Physicians, the Medical Federation is authorising and supervising the physicians. Patients may address complains to “The Chamber of Physicians” who will investigate the matter. The chamber may, in serious matters, withdraw the authorisation of a physician if the law is violated. Most of the complaints are addressed to “the ombudsman” and settled that way.

Not anybody may treat

The practise of medicine without a legal qualification is an offence. According to art.184 of the Penal Code, unskilled persons practising medicine or activities reserved for physicians, risk imprisonment up to three months or a fine. Nevertheless, non-health CAM providers do offer their treatment in Austria.

7.1.3 Reimbursement

Complementary medicines are generally not covered by public insurance. The social insurance may decide to cover CAM in some specific cases. Special cases are when scientifically proven medicine is of little use and the CAM treatment has been experienced being a better choice. Some private insurance companies cover complementary medicines.

7.2 Belgium

7.2.1 Summary²⁸

In Belgium treatment is restricted to legally regulated personnel. The practise of homeopathy, chiropractics, osteopathy and acupuncture is regulated.

7.2.2 Professionals and non-professionals

Legally regulated personnel

Until 1999 the practise of CAM was restricted to physicians, and there were no legal requirements or specific training regarding these techniques. The Order of Physicians promulgated a Code of Professional Ethics that practically forbade the use of CAM. By stating “to diagnose and to establish or pursue a treatment, doctors have to provide attentive and conscientious care in accordance with the present and acquired knowledge of science”. Even though this code was not a law, provincial councils applied it. On these grounds, the disciplinary authorities set limitations on therapeutic freedom.

²⁸ Reference for the chapter where nothing else is noted:

Legal Department, FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu Hoofdbestuur
Directoraat-General Basisgezondheidszorg, 08.07.05

In 1999 the Government of Belgium adopted a law concerning the use of CAM²⁹. The government considered that the population should have freedom of choice concerning therapeutic treatments. However, methods applied are required to be safe, structured and controlled. The law recognises the techniques of homeopathy, chiropractics, osteopathy, and acupuncture and provides for the recognition of other CAM techniques to come. The law provides a structure and a procedure that may lead to the regulation of a CAM therapy, and to the individual registration of practitioners of CAM. It must be mentioned that this law will only take effect after a series of implementing orders have been engaged. The ministry of the federal public service 'Health, Food Chain Safety and Environment' intends to do so. From 1999 persons who comply with the law's conditions and its implementing orders will be able to obtain a license for a recognised technique. According this law the practitioners do not have to be allopathic health personnel. However, it will be forbidden to practise a regulated CAM therapy without a license (individual registration).

Supervising regulated personnel

Commission

The law also foresees the establishment of a commission to advise the government on the practise of CAM regulation. In this commission the representatives of the Faculties of Medicine and the representatives of the different disciplines of CAM are equally represented. This commission will advise with regard to insurance for professionals (including minimum coverage), membership in recognised professional organisations, a system of registration, regulation of advertising and a list of forbidden acts for non-physician practitioners. The commission is also designated to advise the Government on the registration of a CAM therapy and on the conditions for individual registration.

Chambers

A chamber will be established for each discipline of non-conventional medicine. These chambers will represent the non-conventional medicine concerned in the advisory commission. Each chamber will advise on the registration of the practise it's representing and on a system of individual registration for the practise concerned. Each chamber will also advise the government on the organisation of a peer-review system and a code of professional ethics. Moreover each chamber will advise the minister on licensing and on the withdrawal of a given license. In this way it will be possible to sanction those practitioners who do not follow the adopted regulation.

Not anybody may treat

Practising medical acts without a legal regulation is an offence.

7.2.3 Reimbursement

The Belgian social security system does not officially reimburse CAM. However, allopathic physicians using CAM may assure their patients that at least part of their fees will be reimbursed. There are private insurance companies that partly reimburse chiropractics, acupuncture, osteopathic, and homeopathic remedies.

²⁹ Law of 1999 on non-conventional medical practises in Belgium. Text in French: <http://www.health.fgov.be/AGP-Lex/fr/legislation/loi/medecine-non-conventionnelle/loi-medicine-parallele.htm>

7.3 Cyprus³⁰

7.3.1 Summary

In Cyprus treatment is restricted to legally regulated personnel. Chiropractics is regulated.

7.3.2 Professionals and non-professionals

Medical Registration Law regulates what qualifications are needed to practise medical acts, and practising without qualification is an offence. Chiropractics is regulated and a new law is in preparation regulating acupuncturists and osteopaths. Other kinds of alternative treatment are not regulated. However, the practise of the authorities is to follow the amendments of the United Kingdom. If someone is allowed to practise under UK regulations, then they may also practise their alternative activities in Cyprus.

7.3.3 Reimbursement

Information is not available.

7.4 Czech Republic³¹

7.4.1 Summary

In the Czech Republic treatment is restricted to legally regulated personnel. Homeopathy is regulated.

7.4.2 Professionals and non-professionals

Only authorised medical professionals are allowed to carry out medical acts. Homeopathy and acupuncture are tolerated in allopathic medicine. However, the Code of Professional Ethics plays an important role in safeguarding patients. The Code stipulates that physicians will not put patients in their care at risk, even if to influence the patients' condition using methods that is less common in the Czech Republic. In 2002 a new law gave permission to non-physician homeopaths to practise freely³².

7.4.3 Reimbursement

Public Health Insurance does not cover acupuncture and homeopathic preparations. If referred by physicians, the public covers different SPA treatment³³.

³⁰ Ministry of Health, Cyprus 01.12.04 (ministryofhealth@cytanet.com.cy)

³¹ Ministry of Health, Department of International Relations, Czech Republic, 26.10.04

³² WHO global atlas of traditional, complementary and alternative medicine. Kobe, Japan: World Health Organisation, the WHO Centre of Health Development, 2005.

³³ Ibid

7.5 Denmark

7.5.1 Summary ³⁴

In Denmark anybody may treat but law restricts the scope of their activities. Chiropractics is regulated. A voluntary official registration scheme for those who practise CAM has been established.

7.5.2 Professionals and non-professionals

Legally regulated personnel

The Practise of Medicine Act of 1976 regulates the requirements for practising medicine and the authorisation of physicians. Physicians are allowed to use whatever techniques they choose, though the treatment has to be considered as responsible professional conduct. Practitioners of chiropractics were authorised in 1992³⁵. The Danish Board of Health (Sundhedsstyrelsen) is responsible for supervising health services and authorised health personnel in the country.

Anybody may treat-

But some treatments are restricted to legally regulated personnel

The Practise of Medicine Act permits CAM providers to treat regardless of their training and without previous authorisation. However, non-Danish citizens who have not resided in Denmark for at least ten years may not practise complementary medicine.

The Practise of Medicine Act restricts specific medical procedures and treatment of certain diseases to authorised health personnel. Only health personnel may practise the following:

1. Treat persons for venereal deceases, tuberculosis, or any other infectious diseases
2. Perform surgery, administer total or local anaesthetics or provide obstetrics aid
3. Apply medicines which may be dispensed only with physician's prescriptions
4. Use X-ray or radium treatments or therapies using electrical machines.

CAM providers are not permitted to use needles except under the supervision of an allopathic physician. This means that only allopathic physicians have legally provided acupuncture (Supreme Court 1981)³⁶. Violation of the limited monopoly of performing medical procedures and treating certain diseases result in an offence. However, non-allopathic providers may only be prosecuted for exposing patients to a provable danger, or causing them serious deterioration or death³⁷.

³⁴ Referee for the chapter where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

Sundhedsstyrelsen, Denmark 06.09.05

³⁵ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

³⁶ Ot.prp. nr 27(2002-2003) Om lov om alternativ behandling av sykdom mv. Norwegian Health Departement.

³⁷ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

Voluntary registration of CAM providers³⁸

In 2003 the Danish parliament passed a resolution to establish a federation administered register for CAM providers who are not medical doctors (“registered alternative practitioner”). The objective of the regulation is to contribute to safeguarding of the patient and to ensure the rights of consumers who seek registered CAM providers. Organisations approved by the government are given the task to register the providers. To be a “registered” CAM provider, the practitioners must have a membership in a practitioners’ organisation approved by the government and documented knowledge of basic medicines. The register was put into effect 01 June 2004. The register is voluntary and providers will be “self-regulated” through their member associations.

If CAM providers violate the legal rules, the authority or the patients can ask the police to investigate the matter. If CAM providers are “registered” according to the law, violation of the rules of the federation may exclude the person from membership in the federation.

The Practise of Medicine Act safeguards the patient when attending CAM providers, from being treated by unauthorised personnel in cases of some restricted medical procedures and diseases. If the patient seeks “registered” CAM providers, the safeguarding of the patient may be extended to areas comparable to the legal regulation of authorised health personnel. The safeguarding depends on the requirements set by the authorities when approving a federation.

7.5.3 Reimbursement

In general public reimbursement is not available for the use of alternative medicine. However, since 1975, a special agreement between the public insurance schemes and the chiropractors provides partial coverage. Furthermore, some reimbursements for acupuncture and osteopathic treatment are made when registered physicians refer patients. International Health Insurance, Denmark AS, distributes private insurance in Denmark and in several other European countries.

7.6 Estonia³⁹

7.6.1 Summary

In Estonia treatment is restricted to legally regulated personnel. CAM is not regulated.

³⁸ Act of Mai 19th 2004, No 351 Bracheadministrert registreringsordning for alternative behandlere (Register for CAM providers) http://www.vifab.dk/alternativbehandling/regler_og_rettigheder or <http://www.pkn.dk/lovsamling>

³⁹ Health Care Board of Estonia, 17.11.04 and 03.06.05 (<http://www.tervishoiuamet.ee> or <http://www.legaltext.ee>)

7.6.2 Professionals and non-professionals

Legally regulated personnel

Health Service Organisation Act (2001) regulates health care service and health personnel. Only authorised health personnel are allowed to carry out medical acts, and the practise of medicine without a legal qualification is an offence. There is no positive list of health care services. Any service that is provided with the aim to treat patients and cure illness is regarded as health care and only authorised medical professionals can provide it. There are no restrictions of CAM practised by authorised health personnel; they may provide acupuncture, homeopathy, chiropractics etc. However, the treatment has to be considered as “responsible professional conduct”. The authority (The health care Board of Estonia) supervises registered (authorised and licensed) health personnel.

Not anybody may treat

There are no general CAM regulations in the country. According to art.184 of the Penal Code and the Health Service Organisation Act, providers who are not registered with a title may treat patients if they do not pretend to be health care professionals and do not practise within public service. If somebody claims a provider is an intruder to health service, the court will decide. If the court determines the provider is not an intruder, she or he can continue services and this issue is only business matter (pay taxes).

7.6.3 Reimbursement

Public reimbursement is not available for CAM treatment.

7.7 Finland⁴⁰

7.7.1 Summary

In Finland anybody may treat. Chiropractic s, naprapaths, and osteopaths are regulated.

7.7.2 Professionals and non-professionals

Legally regulated personnel

Health care professionals are prescribed in the Act 559/1994 and the Decree 564/1994. Health care professionals include licensed professionals, authorised professionals and professionals with a protected occupational title. The purpose of the Act and the Decree is to promote the safety of patients and to improve the quality of health care services by ensuring that health care professionals have the necessary training to provide medical treatments. The National Authority for Medicolegal Affairs and State Provincial Offices supervises health care professionals. According to Act 559/1194 health care professionals must employ generally accepted, empirically justified methods, in

⁴⁰ The Ministry of health, Finland 19.09.05, <http://www/teo.fi> (National Authority for Medicolegal Affairs) or <http://www/stadia.fi> (Helsinki Politechnic Stadia/Faculty of Health Care and Social Services/Rehabilitation and Social Services/Osteopath)

accordance with their training which must be continually supplemented, but the methods which a health care professional may employ are not regulated more precisely.

Chiropractors (1994), naprapaths (1994), and osteopaths (1993) are categorised as professionals with a protected occupational title. They are accepted as part of the ordinary health service.

Everyone may treat

According to Act 559/1994, other practitioners who are not registered with a title may treat patients if they do not pretend to be health care professionals (by using a protected occupational title). However, the authorities do not supervise them. Acupuncture is not regulated in legislation and persons other than health care professionals may also apply it.

7.7.3 Reimbursement

In general, CAM is reimbursed if given by qualified physicians. Chiropractics, naprapathy, and osteopathy are reimbursed when given in cooperation with physicians. Private insurance reimburse some kind of chiropractic treatment.

7.8 France

7.8.1 Summary⁴¹

In France treatment is restricted to legally regulated personnel. Osteopaths are regulated.

7.8.2 Professionals and non-professionals

Legally regulated personnel

According to the Code of Public Health only authorised medical professionals (physicians, dentists, midwives) and recognised paramedics professionals (working under recommendation of a physician) are allowed to carry out medical acts, and the practise of medicine without a legal qualification is an offence. In addition the Code of Professional Ethics of 1995 plays an important role in safeguarding the patients, especially by stating the rights and duties of practising physicians. In 2002 osteopaths were regulated⁴².

The Order of 1945 has two kinds of regulations for physicians; the first set of rules determines the requirements for the license to practise medicine, the second one provides that the practise of medicine would unfold under the authority of the National

⁴¹ Reference for the chapter where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

⁴² Social and Health Directory, Norway. Report about Osteopathy, Naprapathy and Manuel therapy. Oslo: 2005.

Order of Physicians, which is itself under the supervision of the Council of State. The Council of State and the Order of Physicians are designated as disciplinary authorities.

In general the French Academy of Medicine has not recognised the validity of alternative medicine. The Code of Ethics states that physicians may not propose cures to their patients, which are insufficiently proved, and that physician have to use scientifically proven methods. When authorised health personnel practise CAM, they may be prosecuted according to the Code of Professional Ethics. This may lead to disciplinary sanctions; however, the authorities are becoming more tolerant towards the practise of CAM by authorised health personnel. In the later years the practise of chiropractics, osteopathy and acupuncture are by the medical orders considered as “responsible professional conduct”.

Supervising regulated personnel

According to the law, the professional medical orders (like the National Order of Physicians) supervise health services and health care personnel and ensure fulfilment of laws and regulations. Therefore, they have a public mission although they are private institutions. They have to elaborate general rules of practise, particularly the Professional Code of Ethics. The Orders also have to ensure the enforcement of professional rules through administrative controls. The Order can withdraw the registration in the Order (and thereby the license to treat) of health personnel if the law is violated. If the violation is serious, the Order may also ask the police to investigate the matter. The professions, which are not organised in Orders, are under the surveillance of public authority, which have the same functions and play the same role as the existing professionals Orders.

Not anybody may treat

The practise of medicine without a legal qualification is an offence. There are no specific legal regulations of CAM in the country. The Code of Public Health includes rules regarding the illegal “practise of medicine”. Performing a medical act reserved to authorised personnel is an offence. Three categories are specified as “practise of medicine”; making a diagnosis, prescribing a treatment, and performing some medical acts. In addition to the medical acts usually reserved for physicians, the following list is strictly restricted to physicians:

1. all manipulations of joints, enclosing slipped disc, osteopathy, vertebra therapy and chiropractics;
2. prosthetic massage;
3. gynaecologic massage;
4. specific physiotherapeutic acts;
5. methods for removal of hair, expect for methods using tweezers and wax;
6. abrasion of teguments
7. handling of a machine determining the ocular refraction;
8. tonal audiometry.

French law has been very repressive with regard to the illegal practise of medicine and intrusion of medical professions. Any non-allopathic provider in the field of medicine providing any of the acts defined as “practise of medicines” may risk lawsuit, but the current trend is rather to impose lighter sentences on these issues. Providing CAM is not illegal when referred to as a counselling service not intruding on health service and the practise of medicine.

7.8.3 Reimbursement

The social security system, as well as some private insurance companies, reimburses a number of complementary treatments (mostly acupuncture sessions and homeopathic prescriptions) provided by physicians.

The social security system designates physicians using complementary medicines as “doctors with a particular type of practise” (MEP). A MEP indicates a physician’s orientation, without any guarantee of the quality of care.

7.9 Germany

7.9.1 Summary ⁴³

In Germany treatment is restricted to legally regulated personnel (health personnel and Heilpraktikers). The law restricts the scope of Heilpraktikers` activities.

7.9.2 Professionals and non-professionals

Legally regulated personnel

Only medically qualified personnel and licensed Heilpraktikers may practise medicine (heilkunde). The Individual Health Care Professions Act and the Social Code Book V regulate the requirements for practising medicine and the regulation and authorisation of health personnel.

When authorised health personnel practise alternative treatment within the scope of the health service, the alternative treatment has to be considered as responsible professional conduct and be given by duly qualified medical personnel. The authority supervises health personnel and ensures fulfilment of laws and regulations. The authority can withdraw the authorisation of health personnel if the law is violated, and if the violation is serious, the health authority may also ask the police to investigate the matter.

The law on Heilpraktiker introduced in 1939, licenses practitioners who are not members of a recognised health professions to practise⁴⁴. The main intension of the law is to secure that the treatment of Heilpraktikers does not negatively affect the public health. The Lander (provincial government) is administering the system. To obtain a Heilpraktiker license the candidate must pass an examination in basic medical knowledge, be at least 25 years old, have a German or EU citizenship, have completed primary school, have a good reputation, and have a medical certificate. The law restricts specific medical procedures and treatment of certain diseases to authorised health personnel. Heilpraktikers are not allowed:

1. to practise dentistry
2. to treat sexual diseases

⁴³ Reference for the chapter where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

and Bundesministerium für Gesundheit, Germany 07.06.05

⁴⁴ Heilpraktikergesetz: <http://www/med-con.de/html/hpg01.html>

3. to treat communicable and epidemic diseases
4. to deliver certain medications (drugs)
5. to give or provide anaesthetics and narcotics
6. to practise obstetrics and gynaecology
7. to X-ray
8. to practise autopsies and to deliver death certificates

Regarding ethical rules, the Heilpraktikers' organisations issue a professional Code of Practise. The code of practise provides that Heilpraktikers are conscious of the limit of their knowledge and skills, that they have concern of professional secrecy, give the patients clear explanations concerning their illness and the treatment they provide as well as the length and the dangers of the treatment, and that they have an obligation to refer the patients to a specialist when practitioners do not have sufficient knowledge to treat them. However, this code of practise cannot be compared with the professional public regulation regarding allopathic medical professionals (physicians). This code of practise does not incorporate rules with regard to knowledge and skills necessary to practise responsible professional conduct.

If Heilpraktikers violate the legal rules, the authority or patients can ask the police to investigate the matter. Violations of the limited monopoly of performing medical procedures and treating certain diseases result in an offence.

If patients attend a Heilpraktiker, the Code of Practise will not safeguard the patient in the same way as the legal regulation of authorised health personnel does. However, the legal code will protect the patient in serious matters.

Not anybody may treat

The practise of medicine without a legal qualification is an offence. According to the Penal Code, unskilled persons practising medicine or activities reserved for authorised and licensed personnel, risk imprisonment or a fine.

7.9.3 Reimbursement

Public and private reimbursement is only available for CAM given by authorised health personnel. However, some private insurance companies also reimburse treatment not scientifically recognised if they are provided by Heilpraktikers and if their effectiveness is not completely rejected⁴⁵.

7.10 Greece⁴⁶

7.10.1 Summary

In Greece treatment is restricted to legally regulated personnel. CAM is not regulated.

⁴⁵ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

⁴⁶ Ministry of Health and Social Solidarity, Division of International Relations, Greece 11.07.05 (intrel@mohaw.gr)

7.10.2 Professionals and non-professionals

Only legally regulated personnel are allowed to treat patients. Physicians practise acupuncture and homeopathy. There is no legislation covering the field of CAM in Greece. Consultants may provide some CAM⁴⁷.

7.10.3 Reimbursement

Information is not available.

7.11 Hungary

7.11.1 Summary⁴⁸

In Hungary treatment is restricted to legally regulated personnel (health personnel and licensed “Nature doctors”). CAM is regulated.

7.11.2 Professionals and non-professionals

Legally regulated personnel

The final report of the European Commission sponsored COST project on Unconventional Medicine is describing the legal regulation in Hungary as follows:

Government Decree No 40/1997 “Korm. on the Practise of Alternative Medicine”⁴⁹, recognises CAM as an alternative approach to health and illness. According to this legislation CAM has become a legitimate part of the health care system complementing scientifically based medical practise. Physicians must be certified in therapies of CAM to offer treatment. Health personnel without higher academic qualifications and other providers must, in addition to being certified in CAM therapies, document knowledge of health communications and health duties. Health duties may be requirements of responsible professional conduct, confidentiality, documentation and ethical rules. The non-health provider has in addition to pass a health-exam in order to practise. Following a successful examination, providers of CAM can be given a license to practise. There are three categories of authorised medical practitioners, physicians, practitioners with a non-academic higher health qualification and other practitioners. The term “Natural doctors” refers to authorised practitioners from all three categories. The Public Health Service is in charge of licensing in the same manner as for ordinary health personnel.⁵⁰

In fall 2005 a new law will be established, regulating only two groups of CAM practitioners, physicians with CAM license and Natural Medicine Professionals. Physiotherapists will be licensed as CAM practitioners without any further exam and acupuncturist working with drug addicts may be licensed although not being physicians. The authorities are also investigating the possibilities of licensing practitioners who are not physicians, like manual therapists, chiropractics and providers of neuraltherapy.

⁴⁷ European Council for Classical Homeopathy, information given 21.09.05

⁴⁸ Reference for the whole chapter where nothing else is noted:

The Ministry of Health, Social and Family Affairs, Hungary, meeting in Budapest 29.04.05.

⁴⁹ An English version of the law text can be asked for at the Ministry of Health, Hungary.

⁵⁰ Monckton J, the Research Council for Complementary Medicine. The final report of the European Commission sponsored COST project on Unconventional Medicine. May 1999.

http://www.rccm.org.uk/static/Report_COST.aspx?m=0

Order 11/97 of the Minister of Welfare determines that a medical doctor shall govern diagnosis and therapy, and CAM practitioners may only complement the physician's activity⁵¹. Non-physician "Natural doctors" are therefore allowed to practise when they work under the supervision of a physician or when they intervene after a physician's diagnosis. When a patient desires to be treated by a "Natural doctor", her/his consulting physician may not oppose her/his choice. Thus, the right to choose one's medical practitioner is guaranteed by law.

Every licensed CAM practitioners is not allowed to practise all therapies of CAM. The order 11/97 identifies those therapies only allowed by physicians with CAM license, and it identifies which therapies every "natural doctor" may provide. These are:

1. Activities to be carried out only by a medical doctor (high level):
Homeopathy, Manual medicine, Traditional Chinese medicine (Acupuncture), Ayurvedic medicine, Traditional Tibetan medicine, Biological dentistry and Anthroposophic medicine.
2. Activities that can be practised without a MD degree (middle level):
Acupressure, Alternative gymnastics and massage, Lifestyle therapy, Reflexology, Alternative physiotherapy, Bioenergy, Phytotherapy (Herbalism) and Kinesiology.

Supervising regulated personnel

In Hungary, any health care activity needs to be licensed and controlled by the National Public Health and Medical Officers' Service. Authorised "Natural doctors" have to respect obligations and ethical rules and keep the patient record in the same way as authorised health personnel. The Medical Officer's Service is in charge of supervising the activities of all licensed personnel. The Service controls their qualification, the facility and equipment of the clinic as well as the professional nature of the activities carried out.

Not anybody may treat

According to the law, it is illegal providing CAM without an authorisation. However, the authorities find it difficult to set the demarcation line between health service and service for well being. Some few serious cases are taken to the courts.

7.11.3 Reimbursement

The social insurance covers CAM treatment given by CAM licensed physicians, physiotherapists and acupuncturists. The public does not reimburse homeopathic medicines.

7.12 Iceland

7.12.1 Summary⁵²

In Iceland anybody may treat but law restricts the scope of their activities. Chiropractors and osteopaths are regulated. A voluntary official registration scheme for those who practice CAM has been established.

⁵¹ Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

⁵² Ministry of Health and Social Security, Iceland 28.09.05.

7.12.2 Professionals and non-professionals

Legally regulated personnel

The Physicians' Act (1988) regulates the requirements for practising medicine and the authorisation of medical doctors. Other laws and regulations regulate other health personnel. Chiropractors (1990) and osteopaths (2005) are authorised health personnel. There are no restrictions regarding the use of CAM other than relating to harmful acts and serious diseases. When authorised health personnel practise alternative treatment within the scope of the health service, the legal rules of the health personnel applies. The authorities supervise all authorised health personnel.

Anybody may treat-

But some treatments are restricted to regulated personnel

CAM providers are allowed to provide health related services (CAM) regardless of their training and without previous authorisation. According the Physicians' Act only physicians may use the title medical doctor, provide medical treatment, and prescribe medications⁵³.

In 2005 the Icelandic Parliament (Althingi) passed the Healers Bill and Healers regulation⁵⁴. The act establishes a voluntary official register for CAM providers. The objective of this new law is "to contribute to safety for those who seek and use healers' health related services (CAM), and to ensure the quality of the services as far as possible". CAM Providers are not allowed to provide their services in cases of serious disease nor are they allowed to do any medical procedures or use harmful treatment. Health personnel only may practise the following:

1. Medical intervention or treatment that may entail a serious health hazard.
2. Treatment of communicable diseases that is hazardous to public health.
3. Treatment of serious diseases and disorders.

This provision does not apply if the treatment takes place in cooperation with or in consultation with the patient's physician.

The law contains requirement of confidentiality concerning patient information and requirements of current insurance for all CAM providers. Violations of the monopoly of performing medical procedures and treating certain diseases result in an offence.

Voluntary registration

The Healers Act establishes a voluntary official registration scheme for those who practise CAM. Proposed "Draft regulations on voluntary registration system for healers" describe the registration. The objective of this regulation is "to conduce to safety of those who seek or use healers' health related services, and to ensure the quality of the service as far as possible". The register will include providers who have had a basic health education, have accomplished some practisal training under supervision, hold current insurance and are members of an approved organisation. Contrary to the arrangement in the other Scandinavians countries, there is a possibility in Iceland to become "registered" without being a member of an approved organisation if the provider fulfils specific conditions listed in the law. The "Federation of Icelandic

⁵³ Ot.prp. nr.27 (2002-2003) About Act relating to the alternative treatment of illness, ect. Health Department Norway.

⁵⁴ Ministry of health and Social Security, Iceland

<http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/lawsandregulations> or <http://www/landlaeknir.is>

Healers” will take on the necessary tasks for registration and maintaining the register. The register will be voluntary and providers will be self-regulated through their member associations.

7.12.3 Reimbursement

Public reimbursement is not available for complementary/alternative medicine⁵⁵.

7.13 Ireland

7.13.1 Summary

In Ireland anybody may treat but law restricts the scope of their activities.

7.13.2 Professionals and non-professionals

Legally regulated personnel

The Medical Practitioners Act (1978) regulates the requirements for practising medicine and the authorisation and registration of physicians⁵⁶.

Anybody may treat-

But some treatments are restricted to authorised health personnel⁵⁷

CAM providers are allowed to practise, but law restricts the scope of their activities. Although allopathic physicians do not have a legal monopoly on medical practise, only registered doctors are allowed to:

1. treat venereal diseases;
2. practise in obstetrics;
3. certify death;
4. issue medical certificates for official purpose;
5. prescribe a wide range of controlled drugs;
6. give advice in court on specific issues;
7. supply service to the police for alcohol linked road traffic offences;
8. administer anaesthetics.

CAM providers are allowed to practise medicine regardless of their training and without previous authorisation providing that they do not infringe the Medical Practitioners Act of 1978. It is an offence for non-registered providers to practise medical treatment under the pretence of being a registered practitioner.

⁵⁵ Ot.prp. nr.27 (2002-2003) About Act relating to the alternative treatment of illness, ect. Health Department Norway.

⁵⁶ Maddalena S. The legal status of complementary medicines in Europe. Berne: Universitè de Neuchâtel, Stämpfli Publisher Ltd. 1999.

and Department of Health and Children 17.12.04, <http://www.irishstatutebook.ie/front.html>

⁵⁷ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

Voluntary registration⁵⁸

In 2001 the Minister of Health and Children appointed a work-group to examine and explore the practical issues involved in establishing appropriate regulation for CAM providers. The report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland was launched in November 2002.

The following is a summary of the main recommendations in the report:

1. The consultation process should be continued.
2. Self-regulation of individual therapies should be strengthened.
3. Individual therapies should be encouraged to establish registers of qualified members. As part of the consultation process, a National Working Group should be set up to examine and consider regulatory issues in Ireland.

During 2005 the government is preparing a law offering a voluntary register of CAM providers administered by the federations⁵⁹.

7.13.3 Reimbursement

Public reimbursement is available for CAM provided by physicians⁶⁰.

7.14 Italy⁶¹

7.14.1 Summary

In Italy treatment is restricted to legally regulated personnel. Chiropractics is regulated.

7.14.2 Professionals and non-professionals

Legally regulated personnel

Only authorised medical professionals are allowed to carry out medical acts, and according to a decision of the Criminal Supreme Court of Appeal, physicians are allowed to practise CAM. The National Federation for the Orders of Doctors and Dentists has formally recognised acupuncture, chiropractics, homeopathy, phytotherapy, anthroposophic and ayurvedic medicine as legitimate forms of health care⁶². Chiropractors are considered as medical auxiliaries. Thus, the practise of chiropractics

⁵⁸ Health service Development Unit: Report on the Regulation of Practitioners of Complementary and Alternative Medicine in Ireland. Ireland 2002.

⁵⁹ National Working Group on the Regulation of Complementary Therapist. Department of Health and Children. Ireland 15.08.05

⁶⁰ Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

⁶¹ Reference for the chapter where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999. and Ministero della Santa, Italy 09.09.05

⁶² Acupuncture Today. September 2002; Vol 03, Issue 09.

<http://www.acupuncturetoday.com/archives2002/sep/09italy.html>

by non-physicians is tolerated when chiropractors work under the supervision of a physician.

However, the Code of Professional Ethics of 1995 plays an important role in safeguarding the patients. The Code stipulates that physicians are responsible for the choice of alternative means instead of consolidated scientific experiences.

Not anybody may treat

CAM providers are seldom prosecuted despite national legislation that establishes a medical monopoly and that performing medical acts without a regulation is an offence.

7.14.3 Reimbursement

Both public and private reimbursements are available for CAM when provided by physicians, with the exception of chiropractics that is also reimbursed when provided by non physicians.

7.15 Latvia⁶³

7.15.1 Summary

In Latvia treatment is restricted to legally regulated personnel. CAM is not regulated.

7.15.2 Professionals and non-professionals

Legally regulated personnel

Only authorised medical professionals are allowed to carry out medical acts, and only doctors certified in the field of CAM may practise CAM legally. A certificate of CAM treatment has to be renewed after a period of five years. Homeopathy and acupuncture have status as clinical specialities in allopathic medicine.

Physicians with a certificate to provide CAM are supervised by a commission of experts, which counts members of medical associations, in cooperation with representatives of the Medical Society of the Republic of Latvia.

Not anybody may treat

Non-allopathic providers are not allowed to practise CAM, even if they work under the supervision of a recognised health professional. However, non-allopathic providers practise CAM, and in these cases the Administrative Codex provides for a penalty for unauthorised medical practise. However, patients very seldom take legal proceedings against CAM providers.

⁶³ Reference for the chapter where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

7.15.3 Reimbursement

CAM is generally not covered by compulsory health insurance. Acupuncture and homeopathy are exceptions. Private insurance has since 1998 covered legally provided CAM.

7.16 Liechtenstein⁶⁴

7.16.1 Summary

In Liechtenstein anybody may treat but law restricts the scope of their activities. Chiropractics is regulated.

7.16.2 Professionals and non-professionals

Legally regulated personnel

The Health Law of 1985 regulates the health care professions. Only authorised / licensed medical professionals are allowed to carry out what law defines as medical acts. Law does not regulate the practise of CAM, and therefore the physicians are allowed to use the techniques without having to pass a supplementary exam. However the Health Law states “physicians have to practise only in their speciality and according to their knowledge, with the exception of emergency”. Chiropractors are considered to be medical professionals (1985).

Anybody may treat-

But some treatments are restricted to legally regulated personnel

Article 184 of the Penal Code, relating to illegal practise of medicine, specifies that “a person, who without having the necessary training for the medicine’s practise, performs medical acts that are legally reserved medical doctors (defined in the Health law), can be punished.” According to the Health Law the following acts are not considered as acts of health care professions and may be practised by non-allopathic providers:

1. natural medicines,
2. i.e. health care which does not consist
 - a. in body’s intrusions,
 - b. in delivery acts,
 - c. in the treatment of infectious diseases and
 - d. in the prescription of medication”.

There are few court rulings regarding the enforcement of these articles. Thus, in practise, non-allopathic providers are allowed to practise CAM. They only need a commercial authorisation.

⁶⁴ Reference for the chapter where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.
and Office for Public Health, Liechtenstein 13.09.05 and 07.10.05

7.16.3 Reimbursement

CAM is not covered by the compulsory Social Insurance but some private insurance covers CAM.

7.17 Lithuania⁶⁵

7.17.1 Summary

In Lithuania treatment is restricted to legally regulated personnel. Cam is not regulated.

7.17.2 Professionals and non-professionals

There is no legislation covering the field of CAM in Lithuania, but physicians may practise several therapies of CAM considered being “responsible professional conduct”. To practise Homeopathy physicians need a certificate of training from the university.

7.17.3 Reimbursement

Information is not available.

7.18 Luxembourg⁶⁶

7.18.1 Summary

In Luxembourg treatment is restricted to legally regulated personnel. CAM is not regulated.

7.18.2 Professionals and non-professionals

Legally regulated personnel

Only authorised / licensed medical professionals are allowed to carry out medical acts, and treatment, diagnosis and prevention are restricted to members of the medical corpus. The Code of Professional Ethics states that it is unethical for allopathic physicians to recommend to their patients therapies that are based on methods, which are not scientifically proven. Law does not regulate the practise of CAM, however the Ministry of Health has started to look into the field of CAM, and regulation is expected.

Not anybody may treat

⁶⁵ Ministry of Health Care, Lithuania, 18.11.04

⁶⁶ Reference where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

and Ministry of Health, Luxembourg, 01.12.04

Concerning practise of medicine, the law stipulates that persons without the required qualifications, who practise or participate in the diagnosing or treatment of real or supposed pathological disorders, can be prosecuted. Non-allopathic providers using complementary medicine are regularly prosecuted.

7.18.3 Reimbursement

Officially there is no public reimbursement of CAM, with the exception of homeopathy. However, if CAM is provided by regulated health care personnel and according to the legal rules in the field, complementary medicines are, unofficially reimbursed. There is no private insurance available for the coverage of CAM.

7.19 Malta⁶⁷

7.19.1 Summary

In Malta anybody may treat but law restricts the scope of their activities. Acupuncture, osteopathy and chiropractics are regulated.

7.19.2 Professionals and non-professionals

Legally regulated personnel

Licensed and registered medical professionals are allowed to practise medicine. In the Health Care Professions Acts the professions recognised by law are listed. No person shall practise any of the professions complementary to medicines unless his/her name is entered in the respective register kept by the Council for the Professions Complementary to Medicine. Acupuncture, osteopathy and chiropractics are among the recognised professions listed. According to the law, an allopathic physician registered to practise in Malta must refer all persons to be treated by traditional medicines, including acupuncture. Allopathic physicians may practise CAM.

Anybody may treat-

But some treatments are restricted to regulated personnel

CAM providers are not legally regulated in Malta. It is stipulated in the law that non-allopathic providers are not allowed to perform procedures reserved for recognised allopathic medical professions such as physicians, physiotherapists, and pharmacists. However, it is not prohibited for CAM providers to practise medicine.

Although there are no legal sanctions on CAM providers themselves, a breach of the regulation in the law constitutes a criminal offence. There are also restrictions on advertising treatments and clinics.

⁶⁷ Maddalena S. The legal status of complementary medicines in Europe. Berne: Universitè de Neuchâtel, Stämpfli Publisher Ltd. 1999.
and Ministry of Health, the Elderly and Community Care. Malta 23.11.04 and 28.09.05
(euaffairs.mhec@gov.mt)

7.19.3 Reimbursement

Malta does not have a reimbursement system. Consequently they do not reimburse CAM.

7.20 The Netherlands

7.20.1 Summary⁶⁸

In The Netherlands anybody may treat but law restricts the scope of their activities. CAM is not regulated.

7.20.2 Professionals and non-professionals

Legally regulated personnel

The Individual Health care Professionals Act (the BIG Act 1993)⁶⁹ regulates the health personnel, focusing on the quality of professional practise and patient protection. The law has been implemented in stages. The purpose of the act is to foster and monitor high standards of professional practise and to protect the patients against professional carelessness and incompetence. The act contains provisions relating to the protection of titles, registration, reserved procedures and medical disciplines. According to the act professionals can be regulated in two ways. Section 3 lies down rules governing eight professions (medical doctor, dentist, pharmaceutical chemist, health care psychologist, psychotherapists, midwife and nurse). Section 34 regulates the paramedical professions (e.g. speech therapist, dental hygienist and dietician). Reserved procedures may be carried out only by to groups of medical practitioners; those with direct authorisation (doctors, dentists and midwives) and those who may perform the procedures under the instruction of the former (and thereby authorised).

The Individual Health Care Professionals Act lays down disciplinary norms that apply to professionals registered under section 3. The professionals may use CAM treatment, following “due care” and “proper practise”, and that the therapies are not restricted by the reserved procedures. The disciplinary norms and the civil law (penal code) can be used in conjunction with one another.

Supervising regulated personnel

The authorities supervise health personnel regulated in section 3. CAM therapies provided by these professions are restricted by the reserved procedures and the disciplinary code in the act. The authorities can withdraw the authorisation of health

⁶⁸ Referee for the chapter where nothing else is stated:

Ministry of Health, Welfare and Sports and
Public health Supervisory Service of the Netherlands, The Inspectorate of Health Care region South East,
The Hague, meeting 26.04.05.

⁶⁹ More information about the BIG Act: <http://www.bigregister.nl> or <http://www.verwijspunt.nl>

personnel if the law is violated. If the violation is serious, the authority of health may also ask the police to investigate the matter.

Anybody may treat-

But some treatments are restricted to authorised health personnel

Since 1997, according to the Health care Professionals Act, CAM providers are allowed to treat. They are not, however, recognised as official health care personnel, their titles are not protected, they are not integrated into the national health care system, and they are not under the direct supervision of the authorities.

According to the law, specific medical procedures and treatment of certain diseases are restricted to authorised health personnel, except when under the order of a medical professional with direct authorisation. Authorised health personnel only may practise the following:

1. surgical procedures
2. obstetric procedures
3. catheterisations and endoscopies
4. punctures and injections
5. general anaesthetic
6. procedures involving the use of radioactive substances and ionising radiation
7. cardioversion
8. defibrillation, electroconvulsive therapy
9. lithotripsy
10. artificial insemination

The list of the reserved medical acts is not exhaustive and additions are possible.

Violations of the limited monopoly can result in an offence.

The government is not legally regulating any CAM or licensing any providers. The restriction of some procedures and the penal code is protecting the patient while attending the provider. The penal code has rules about abuse and neglect. That means that a person in whom a patient has trust must not mislead the patient, thus making it possible for the patient to be harmed. CAM therapies are commonly in use as preventive medicine and as self-cure. The Individual Healthcare Professionals Act guarantees the patients' complete freedom of choice of providers and, at the same time, includes preventive measures to avoid any potential risk to harm patients' health.

7.20.3 Reimbursement

There are no public reimbursements of CAM. Private insurance offers a package covering for the most used forms of complementary medicine when provided by a medical doctor.

7.21 Norway

7.21.1 Summary

In Norway anybody is allowed to treat but law restricts the scope of their activities. Chiropractics is regulated. A voluntary official registration scheme for those who practice CAM has been established.

7.21.2 Professionals and non-professionals

Legally regulated personnel

The Health Personnel Act regulates the requirements for practising medicine and authorisation / licensing of health personnel⁷⁰. Chiropractic practitioners were authorised in 1988. According to The Supervision Act⁷¹, the authority (Board of Health) supervises health services and health care personnel and ensures fulfilment of laws and regulations. The Board of Health can withdraw the authorisation of health personnel if the law is violated. If the violation is serious, they may also ask the police to investigate the matter.

Anybody may treat-

But some treatments are restricted to regulated health personnel

CAM providers are allowed to practise alternative treatment regardless of their training and without previous authorisation, but some medical procedures and the treatment of some serious diseases are restricted to health personnel. CAM providers are, however, not recognised as official health care personnel, their titles are not protected, they are not integrated into the national health care system, and they are not under the supervision of the authorities.

A new law about alternative treatment was implemented 01.01.2004⁷². The objective of this law is “to contribute to safety for the patients who seek and receive alternative treatment and to regulate the right to practise such treatment”. The law makes the restrictions that health personnel only may practise the following specific procedures and treat the following diseases:

1. Medical intervention or treatment that may entail a serious health hazard.
2. Treatment of communicable diseases that is hazardous to public health.
Non-health personnel may nevertheless administer treatment in cases where the sole purpose is to alleviate or moderate symptoms or consequences of the disease or disorder or side effects of given treatment or where the purpose is to strengthen the body's immune system or its ability to heal itself.
3. Treatment of serious diseases and disorders.
Non-health personnel may nevertheless administer treatment in cases where the sole purpose is to alleviate or moderate symptoms or consequences of the disease or disorder or side effects of given treatment or where the purpose is to strengthen the body's immune system or its ability to heal itself.

The provision in the first paragraph does not apply if the treatment takes place in cooperation with or in consultation with the patient's physician and the patient is of age and is entitled to consent to healthcare pursuant according to the Patient's Rights Act. This also applies to other patients if the health service has no curative or palliative treatment to offer the patient.

The law contains a requirement of confidentiality concerning patient information, which is quite similar to the requirement in the Health Personnel Act.

According to the law covering alternative treatment, “any person who wilfully or through gross negligence infringes the provisions of the act or provisions issued in pursuance of the act, or who is an accessory thereto, may be punished by fines or by a term of imprisonment” but not for more than three months. This also concerns “non-

⁷⁰ Act of July 2nd 1999 No. 64 Relating to health personnel etc.

⁷¹ Act of March 30th 1984 No. 15 About supervision

⁷² Act of June 27th 2003 No. 64 About alternative treatment of illness etc.

Norwegian laws in English text: <http://www.ub.uio.no/ujur/ulov/english.html>

health providers who by medical intervention or treatment wilfully or through gross negligence place a person's life or health in serious danger, either by the treatment itself, or because the patient as a result of the treatment does not seek expert help". Public prosecution may be instituted. However, non-allopathic providers are only prosecuted for exposing patients to a provable danger, or causing them serious deterioration or death⁷³.

Voluntary registration of CAM providers⁷⁴

The act regarding alternative treatment also imposes the government to establish a voluntary official registration scheme for those who practise CAM. The regulation of this register was implemented 1.01.2004. The objective of the regulation is to contribute to increase safeguarding of the patient and to ensure the rights of consumers who seek registered CAM providers. The regulation is also meant to contribute to trustworthy commercial conditions among the providers of alternative treatment. To be registered, the practitioner must have a membership in a practitioners' organisation approved by the government and have a current insurance.

If a CAM provider violates the legal rules, the Board of Health or patients can ask the police to investigate the matter. As CAM providers are considered to be self-employed, the consumers' authority supervises the law. If a CAM provider is "registered" according to the law, violation of the rules of the federation may exclude the person from membership in the federation.

The act regarding alternative treatment safeguards all patients concerning the area of confidentiality, and against being treated by unauthorised personnel, in cases of some restricted medical procedures and diseases. If the patient seeks a "registered" CAM provider, the safeguarding of the patient may extend to areas comparable to the legal regulation of authorised health personnel. The safeguarding depends on the requirements set by the authorities when approving a federation. Also, the legal code will protect the patients in serious matters.

Marketing

The law of alternative treatment also regulates the marketing of CAM providers. The law expresses that "persons providing alternative treatment may in marketing their activity only give an objective and factual description of the nature of their activity". The Consumer Ombudsman (CO) is an independent administrative body with the responsibility of supervising measures in the market.

7.21.3 Reimbursement

Public reimbursement is not available for complementary/alternative medicine. Norwegian Health Insurance offers private coverage of certain types of complementary medicine. The company has a connection to International Health Insurance, Denmark AS, which distributes insurance in several European countries. The insurance covers acupuncture performed by licensed medical doctors as a part of medical treatment.

⁷³ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

⁷⁴ Forskrift om frivillig registrering for utøvere av alternative behandling. Departement of Health. Norway: 11 December 2003.

7.22 Poland⁷⁵

7.22.1 Summary

In Poland treatment is restricted to legally regulated personnel. CAM is not legally regulated.

7.22.2 Professionals and non-professionals

Legally regulated personnel

The Health Care Service Centre Act regulates health care provided by health care service centre and health personnel (medical professions). Consequently alternative medicine services which fall within the scope of the definition of health care services may only be performed by health care services centres and by health personnel. For example, the following CAM services are to be treated as health care services (must be performed by medical personnel): acupuncture (except in case of chronic pain), magnetotherapy with use of magnetic field, laseropuncture, acupressure, zootherapy, diagnosis and therapy concerning alternative, folk and oriental medicine (this list is not a closed one).

Poland is preparing a legal regulation of CAM. The Ministry of Health, by regulation from July 2002, set out the Council to Affairs of Alternative Methods of Therapy, as an auxiliary body of Ministry of Health. The duties of the council are as follows: preparing essential assumptions in order to regulate in legal provisions the alternative methods of therapy issues, in particular the conditions of conducting activity in this scope, rules of obtaining permissions to conduct such an activity, rules of cooperation of the persons conducting such an activity with doctors, preparing assumptions concerning the control in the scope of observing provisions.

7.22.3 Reimbursement

Public resources do not finance alternative treatments.

7.23 Portugal⁷⁶

7.23.1 Summary

In Portugal treatment is restricted to legally regulated personnel. Acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractics are regulated.

⁷⁵ Department Prawnny, Ministerstwo Zdrowia, Poland, 24.06.05 and Ministry of Health, Accreditation Bureau, Poland, 16.11.04

⁷⁶ Referee where nothing else is stated: European Council for Classical Homeopathy. Facts about Homeopathy and other CAM Therapies, Second Edition August 2004. <http://www.homeopathy-ecch.org/newsevents.html>

7.23.2 Professionals and non-professionals

Legally regulated personnel

In July 2003 the Portuguese parliament voted in favour of new laws that recognise the practise of acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractics⁷⁷. The law ensures the right of the Portuguese citizens to freely choose a particular therapy they wish, and also regulates the practitioners who may practise these therapies as independent health care professionals. The Ministry of Education and Science controls the education and certification of degrees and diplomas for the practise of the therapies. A license (authorisation) is given when practitioner can provide qualification according this law.

For the safeguarding the patients, the law has claims about the practise of therapies, confidentiality, documentation routines, current insurance, and information about price, duration and prognosis⁷⁸. Under this law the practise of the therapies will be controlled and accredited by the Ministry of Health.

7.23.3 Reimbursement

Information is not available.

7.24 Slovakia⁷⁹

7.24.1 Summary

In Slovakia CAM treatment is restricted to legally regulated personnel. CAM is not regulated.

7.24.2 Professionals and non-professionals

CAM is not officially recognised, and there is no legislation on the field in Slovakia.

7.24.3 Reimbursement

Information is not available.

⁷⁷ Project of law n 263/IX For framing the base of the Non-conventional Medicine and Project of law n 27/IX Legal procedures of the Non-conventional Therapies

⁷⁸ The Directorate for Health and Social Affairs, Norway. Report about Acupuncture and Homeopathy education. October 2004.

⁷⁹ Ministry of Health of the Slovak Republic, 26.11.04

7.25 Slovenia

7.25.1 Summary ⁸⁰

In Slovenia treatment is restricted to legally regulated personnel. CAM is not regulated.

7.25.2 Professionals and non-professionals

Legally regulated personnel

According to Law of Health Services (1992), “health service may be performed with permission of the Ministry of Health by physical persons, if they fulfil the conditions defined by this law”. The health personnel are licensed to practise health service. The Law of Health Care and Health Insurance (1991) defines health service as “the activities, measures and services for reinforcing health, preventing illness, early detection, timely treatment, nursing and rehabilitation of the sick and injured”. The practise of health service without a permit is an offence. In Article 45 it is stated “Health workers and health associates shall perform health services in accordance within the code of medical deontology or within other professional and ethical codes”. And further Article 58 states “Health workers may use only approved and professionally acceptable supplementary traditional and alternative forms of diagnostics, treatment and rehabilitation which are not harmful to the public health and which are approved by the Ministry of Health with the consent of the Medical Ethics Commission”.

An forthcoming regulation (based on Article 59 of the Law of Health Service), which will define the forms of alternative diagnostics, treatment, rehabilitation and prophylaxis that are legally permitted and the conditions for performing such services as well as the licensing procedure, has not been adopted yet. By this lack of regulation, CAM therapy is not allowed in official medical service.

The official standpoint held by the Ethical Commission of the Ministry of Health is that doctors are asked to revoke their medical licenses when they desire to practise treatment that is not part of the official doctrine of medicine.

However, some physicians are offering acupuncture as a complementary treatment of pain. The Slovenian Associations of Acupuncture only issue licenses to member physicians. The authorities do not punish this kind of treatment.

Supervision of regulated personnel

According to the Law of Health Service, supervision of professional health workers is to be executed by competent professional chambers organised by medical federations. During the last years, known to the Ministry of Health, only one physician has lost the license because of practising CAM therapy.

Not anybody may treat

Providing CAM therapies is legal when referred to as counselling service and not health service. An estimated 1200 CAM providers are practising in Slovenia. CAM providers

⁸⁰ Referee where nothing else is stated:
Slovenian Ministry of Health, meeting in Ljubljana 04.05.05.

mostly register as consulting services for healthy life-style. Business owners of registrant CAM activities are obligatory members of Slovene Chamber of Commerce (SCC), with about 150 members at present (May 2005). There are no conditions set by the SCC and there is no professional supervision of the activities. The federation of providers is developing a training program and introducing self-regulation for its members, with the intension of safeguarding the users of their services. Consumers may complain to the federation and SCC. Currently the penal code is the only form of legal protection of consumers.

The Ministry of Health is proposing the regulation of CAM providers. The purpose of the law will be to safeguard and to emphasize that CAM is to be offered only as an additional therapy to medical treatment.

7.25.3 Reimbursement

There are both public and private reimbursements in Slovenia. Reimbursements are covered by what law defines as health services. CAM is not reimbursed.

7.26 Spain⁸¹

7.26.1 Summary

In Spain treatment is restricted to legally regulated personnel. CAM is not regulated.

7.26.2 Professionals and non-professionals

Legally regulated personnel

According to the general health regulations only authorised health professionals are allowed to perform medical acts on patients, and according to the Royal Decree 3166/1966, licensed paramedics (odontologists, psychologists, nurses, physiotherapists) are allowed to perform medical acts only under the supervision of an allopathic physician.

Law 1277/2003 regulates the health services and establishments where such services are provided⁸². The law only recognises conventional therapies that are scientifically recognised, but accepts the physicians' use of natural, homeopathic and similar therapies that have shown efficacy and are secure. However, according to the Spanish Code of Professional Ethics of 1990, non-scientifically proven means as well as the simulation of the making of a diagnosis, or the application of therapeutic treatments, are prohibited. Complementary medicines are not included within the Royal Decree 127/1984 regarding medical specialities. There are no specific legal regulations of CAM in the country.

⁸¹ Reference where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

⁸² Information given by Nuria Borrás, nborrás@clinic.ub.es

Supervising regulated health personnel

The authority has delegated to The Council of Medical Colleges the supervising of physicians. The council may, in serious matters, withdraw the authorisation of a physician if the law is violated.

Not anybody may treat

The practise of medicine without a legal qualification is an offence. The illegal practise of medicine is regulated by the Penal Code stating that if persons without relevant academic certificates practise acts specific to a profession, they risk imprisonment for a period up to twelve months. This includes all intrusions made by non-allopathic providers in the field of medicine. However, providing CAM is not illegal when referred to as counselling service not intruding health service. The state authorities are tolerant to that kind of CAM providing.

7.26.3 Reimbursement

Public reimbursement is not available for CAM treatment. A few private insurance companies provide coverage for CAM.

7.27 Sweden⁸³

7.27.1 Summary

In Sweden anybody is allowed to treat but law restricts the scope of their activities. Chiropractics and naprapathy are regulated.

7.27.2 Professionals and non-professionals

Legally regulated personnel

The Health and Medical Service Act of 1982 regulates the requirements for practising medicine and the regulation and authorisation of health personnel⁸⁴. Practitioners of chiropractics were authorised in 1989 and naprapaths in 1994⁸⁵. Homeopathy and other forms of CAM are not recognised as “responsible professional conduct” and may therefore not be provided by health professionals. Acupuncture of western style may be provided⁸⁶. The authorities supervise all authorised health personnel⁸⁷.

Anybody may treat-

But some treatments are restricted to authorised health personnel

⁸³ Ministry of Health and Social Affairs, Sweden 11.10.05

⁸⁴ Lag om hälso- och sjukvården (1982:763, HSL)

⁸⁵ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

⁸⁶ Ministry of Health and Social Affairs, Sweden 05.10.05

⁸⁷ Lag om yrkesverksamhet på hälso- och sjukvårdens område, 6 kap, (1998:531, LYHS)

CAM providers are allowed to practise medicine regardless of their training and without previous authorisation. They are, however, not recognised as official health care personnel, their titles are not protected, they are not integrated into the national health care system, and they are not under the supervision of the authorities.

According to the Quackery Act, that has been included in The Health and Medical Services (Professional Activity) Act, only authorised health personnel are allowed to perform the following specific medical procedures and give the following treatment of certain diseases:

1. practise general or local anaesthesia
2. provide care with radiological methods
3. practise in a itinerant way
4. treat specific contagious diseases
5. treat cancer, diabetes, epilepsy or pathological conditions associated with pregnancy or childbirth
6. treat a child who is less than eight years old
7. issue written recommendations or instructions for the treatment of patients who were not personally examined by them
8. provide acupuncture
9. test or supply contact lenses⁸⁸

Violations of the limited monopoly of performing medical procedures and treating certain diseases are an offence. However, CAM providers may only be prosecuted for exposing patients to a probable danger, or causing them serious deterioration or death. Providers found guilty of this charge may be judged by the penal law and may be prohibited from working in the health field⁸⁹.

Voluntary registration of CAM providers⁹⁰

On 10 December 2004, the Swedish government sent an inquiry report referred for consideration to establish a voluntary official register for CAM providers who are not medical physicians. The objective of the register is to contribute to the security for the users who seek and receives CAM.

To be registered, the providers must have membership in a practitioners' organisation approved by the government, have documented knowledge of basic medicine and hold current insurance. According to the current draft, the authorities will take on the necessary tasks for registration, but will closely cooperate with participating organisations. The register will be voluntary and providers will be self-regulated through their member associations. The government offices are working with the legislative proposal.

The Quackery Act safeguards all patients from being treated by unauthorised providers in cases of some restricted medical procedures and diseases. The draft on a CAM register does not include any official supervision of CAM providers or their used methods.

⁸⁸ Lag om yrkesverksamhet på hälso- och sjukvårdens område, 4 kap, (1998:531LYHS) The Quackery Act, (on the prohibition of specific practises in the field of health and medical care)

⁸⁹ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

⁹⁰ SOU 2004:123; Ett nationellt register över yrkesutövere av alternativ- eller komplementärmedicin. <http://www.regeringen.se/sb/d/108/a/35339>

7.27.3 Reimbursement

In general, public reimbursement is not available for the use of alternative medicine. However, some reimbursement for acupuncture treatment is made when provided by physicians⁹¹. International Health Insurance, Denmark AS, distributes private insurance in Sweden and several others European countries.

7.28 Switzerland⁹²

7.28.1 Summary

In Switzerland treatment is restricted to legally regulated personnel. Chiropractics is regulated in all 26 cantons.

7.28.2 Professionals and non-professionals

Legally regulated personnel

In Switzerland every canton (26 cantons) is in charge of their own public health system and is free to regulate the medical practise, as they want. There is no national regulation of CAM. Some academic health professions (physicians, pharmacists, psychologists, ect.) are regulated on national level. Chiropractors are regulated by all the cantons, but the government is planning a national regulation in the near future⁹³. Osteopaths are regulated in 8 cantons⁹⁴. All persons legally providing health care may apply homeopathy according to the standards of good medical practise. In some cantons those not medically qualified may practise homeopathy as well. In 1998, The National Medical Association recognised homeopathy and Chinese medicine (including acupuncture) as medical sub-specialities.

Anybody may not treat

In 15 cantons only authorised health personnel are allowed to give treatment to patients, but in some cantons there are exceptions to this general regulation, allowing definite CAM provided by non-physicians. Some cantons also have restrictions to the use of some techniques of CAM. The authorities in many of the cantons are relatively tolerant with regard to the practise of CAM providers.

In 11 cantons (mostly German speaking) only authorised health personnel and licensed personnel are allowed to give treatment to patients. The provider has to pass a state exam to obtain a licence from the state authorities. Most of the cantons also define specific medical acts that are reserved for physicians. Most often these are:

⁹¹ Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

⁹² Reference where nothing else is noted:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

and Swiss Federal Office of Public Health, 12.08.05

⁹³ <http://www.bag.admin.ch/berufe/projektmed/gesetz/d/index.htm>

⁹⁴ Social and Health Directory, Norway. Report about Osteopathy, Naprapathy and Manuel therapy. Oslo 8. Mars 2005.

1. treatment of communicable diseases,
2. treatment of sexual diseases,
3. practising surgery, or giving injections,
4. providing care in obstetrics,
5. prescribing drugs and medications.

The law restricts the scope of activities of licensed personnel, but there are no restrictions as to the use of CAM.

7.28.3 Reimbursement⁹⁵

The law allows reimbursement for therapies whose efficacy is scientifically recognised. Since 1999 basic health insurance scheme has paid for five alternative treatments provided by qualified doctors, like homeopathy, Chinese medicine, acupuncture, anthroposophic medicine, neuraltherapy, and phytotherapy. To maintain the reimbursement for these therapies (except acupuncture) in the future, their efficacy and cost-effectiveness had to be proven by June 30, 2005. In June 2005 the interior ministry said the five therapies failed to meet the criteria on efficacy, suitability and cost-effectiveness laid down in Switzerland's health insurance law, and therefore health insurance would stop paying for the treatment. Treatment by non-allopathic providers is not reimbursed.

Private insurance companies generally propose complementary health care policies including the coverage of CAM.

7.29 United Kingdom of Great Britain and Northern Ireland

7.29.1 Summary⁹⁶

In Great Britain anybody is allowed to treat but law restricts the scope of their activities. Homeopathy is regulated and registered "Osteopaths" and "Chiropractors" are given legally protected titles. A voluntary official registration scheme for those who practise CAM has been established.

7.29.2 Professionals and non-professionals

Legally regulated personnel

The Medical Act of 1983 regulated the authorisation and registration of health personnel. By delegation from the authorities, the registration is being performed by the professionals' own organisations. Only medical practitioners holding a university degree in medicine are officially allowed to practise medicine. However, the law tolerates alternative practitioners without a medical degree.

⁹⁵ www.swissinfo Switzerland's news and information platform. 03.06.05

⁹⁶ Referee for this chapter where nothing else is stated:

Maddalena S. The legal status of complementary medicines in Europe. Berne: Université de Neuchâtel, Stämpfli Publisher Ltd. 1999.

The Medical Act of 1983 does not regulate which forms of therapies registered doctors may practise. Thus, there is no restriction on medical practitioners applying CAM if they have the required skills or qualifications to practise. This means that CAM is considered responsible professional conduct when given by duly qualified medical practitioners. If physicians refer patients to non-allopathic providers during the period of treatment, they keep the clinical responsibility of their patients.

In 1950, the government gave official recognition to homeopathy in the Faculty of Homeopathic Act⁹⁷. This act empowers the Faculty of Homeopathic to train, examine, and confer diplomas in homeopathy to allopathic physicians and other statutory recognised health professionals.

According to the health acts, all authorised health personnel (pharmacists, doctors, physiotherapists, dentists, midwives, nurses, and others) are supervised. By delegation from the authorities, the control of personnel is ensured by the professionals' own organisations. The government designates the Professional Conduct Committee of every professional organisation as disciplinary authorities. They may admonish, suspend and/or dismiss practitioners.

Anybody may treat-

But some treatments are restricted to authorised health personnel

The right to practise without formal recognition is established under British Common Law. CAM providers are allowed to practise medicine regardless of their training and without previous authorisation, providing that they do not infringe the Medical Act of 1983. Despite the principle of freedom to carry out medical acts, this independence is limited by some legal controls. Only registered doctors may:

1. Treat cancer, diabetes, epilepsy, glaucoma and tuberculosis
2. Prescribe controlled drugs
3. Perform specific medical acts such as abortion or treat venereal diseases
(The Cancer Act of 1939, The Venereal Disease Act of 1917)

If acts by CAM providers result in maltreatment, they may be prosecuted under the penal law. Currently, individuals are protected under UK law from incompetence or unskilled therapists by the tort-based common law of negligence.

Statutory registration of CAM providers

The Osteopath Act of 1993 and Chiropractor Act of 1994 are regulating the registration of osteopathy and chiropractics. Registration and supervision are being ensured by the professionals' own organisations. "Registered" practitioners of these two professions have special rights, including the right to use the title of "Chiropractor" or "Osteopath". Generally, in order to become a member of professional organisations, CAM providers have to be covered by insurance and have to adhere to a Code of Professional Ethics.

The Professional Conduct Committee in every professional organisation is supervising its members. The members are supposed to provide responsible professional conduct and practise only when duly qualified. The sanctions available to the Professional Conduct Committee are to admonish, suspend and/or dismiss practitioners.

⁹⁷ Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, (document WHO/EDM/TRM/2001.2). Geneva: World Health Organization, 2001.

In 2003, two reports were published making recommendations for the statutory regulation of herbal practitioners and acupuncturists working in the United Kingdom⁹⁸. In particular, in the interests of the patient safety and choice, it refers to the need for professional herbalists and acupuncturists to be regulated as soon as possible. Regulation will safeguard the quality of treatment and offer a system of sanctions in case of irresponsible professional conduct. By the end of 2005, the UK Department of Health expects that there will be statutory regulation of herbalists and acupuncturists⁹⁹.

7.29.3 Reimbursement

In general, public reimbursement is not available for complementary/alternative medicine, but alternative treatments are available in some hospitals. Private Insurance offers coverage of certain types of complementary medicine when provided by medical qualified personnel.

⁹⁸ Editorial. The journal of alternative and complementary medicine. 2003: Vol 9, no 6.

⁹⁹ <http://www.opsi.gov.uk/acts>