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Quackery  
or  
Complementary Medicine  
A Historical Approach to the Present Situation

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# Foreword

This paper would not have been written were it not for the help I have recieved from many different people on my journey towards its completion.

For some time I have worked as a legal assitant to Gregory Batcheller, General Council to DeNovaStella AB, with medicinal legal issues, with particular focus on natural remedies. His mentorship inspired me to write this paper. I am very grateful for his guidance.

My academic tutor, Professor Kjell-Åke Modéer, helped me transubstansiate my legal interest in the subject area into a historical one. He has supervised and lead me through my work with interesting historical perspectives and ideas. I thank him for his patience and inspiration.

I have recieved advice and ideas from the personnel of the Swedish Medical Agency at seminars on natural remedies held in Stockholm in October of 2004. In particular, I wish to aknowledge Maria Szrimai for an interesting lecture at the seminar and for takning time to answer my questions, as well as the Farm Dr Jan G Bruhn whom I hade the privilege to speak to at said seminar and who provided me with interesting insights into the subject.

Gunnel Wallin and Karin Dutina of the Committee for Alternative Medicine allowed me to attend a meeting with representatives of the Industry, and for this I am very grateful. I was witness to some very interesting discussions which stimulated my further research into certain subject areas.

Though I have not had the opportunity to meet with her in person, I wish to mention Motzi Eklöf as a special source of inspiration. Her thoughts and insights in the subject of complementary medicine have been an important foundation to my own legal views in this paper.

A very special thanks to Mr Philip Horowitz for taking his time to comment this paper.

Last, but certainly not least, I must thank my wonderful Mom and Dad. For everything.

Lund in October 2005

Hedda Lidgard

## Summary

Swedish consumers are increasingly interested in Complementary medicines, yet the Swedish legal attitude appears reluctant to these traditional methods. This thesis examines the historical roots of the alleged Swedish attitude and investigates whether Swedish law and practice is in line with EU requirements. Focus is on the Caregivers and restrictions surrounding their practice and also on the restrictions regarding Complementary medicines used by the actors.

The historical exposition shows a parallel development in the field of medicine in most countries during many centuries in ancient times. However, a major deviation occurred in Sweden compared to other European countries in that the Swedish licensed practitioners were given state monopoly at a very early stage. In 1663, a private medical guild, *Collegium Medicum*, was set up, which changed into a public and official institution only twenty odd years later. The Swedish Medical enactments of 1688 constituted a complete monopoly for the Licensed practitioners in the field of medicine. The reason was not an urge to protect the public from harm, but rather to safeguard groups of qualified professionals and their ability to earn a living.

The 1688 legislation was not replaced until 1915 – more than 225 years later. The 1915 Quackery Law eliminated the medicinal monopoly, legalizing professional health care practice by Paramedical practitioners, yet introduced restrictions for them in dealing with severe health conditions. In parallel, requirements on Science and Verified Experience have in reality prevented the Licensed practitioner from working outside Conventional medicines.

History presents an explanation for the lack of acceptance and respect for Paramedicinal practitioners and Complementary medicines in Sweden. In other European countries Complementary medicines have been tolerated and accepted since long. The methods have been – and continue to be - taught at universities and practiced by licensed professionals.

The historical events give a perspective when investigating the Swedish contemporary legal situation. Swedish national law has been forced to bow to the more tolerant attitude found within the European legislation. Yet, in many situations Swedish law presents narrow interpretations: There is a lack of fiscal neutrality for Complementary medicines compared to Conventional medicines. Restrictions on Licenced practitioners use of Complementary medicine also clearly distinguishes Sweden from the rest of Europe, whereas the exclusion of certain treatments and certain groups of patients for Paramedicinal practitioners appears to be in line with EU law.

The overall conclusion is that Swedish law is in line with EU standards, but that certain attitudes and practices must be revised. Whether the Licensed medical practitioners like it or not, it seems that Complementary medicine is becoming more and more incorporated in the consciousness of the public and gaining the acceptance of society at large.

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# 1. Introduction

## 1.1.1. Background

**QUACK**, one who fraudulently misrepresents his ability and experience in the diagnosis and treatment of disease or the effects to be achieved by the treatment he offers.<sup>1</sup>

A growing number of people, who are increasingly disenchanted with the sterile world of modern Conventional medicine are turning to (natural) alternatives. The reasons for this may include the increasing difficulty in getting the traditional professional help at hospitals and care centres which is due to lack of practitioners. The care that is available is often impersonal and the time available for individual patients limited. Studies show that the use of Complementary medicines has continuously increased since at least 1975<sup>2</sup>. This growing interest is also reflected in legislation in most European countries which purports to protect consumers from quacks and their “wonder drugs”.

The question arises, however, whether certain European countries do not have too restrictive an attitude towards all medications and practitioners not falling under the strict contemporary definitions of *Conventional medicine* and *licensed medical practitioner*. Should everything falling outside these categories be considered quackery?

One can divide medicinal remedies into three categories: those that are *respected*, those that are *tolerated* and those that are *not tolerated*. This paper is interested only in those falling into the second and third categories – that is, those which are not completely respected. In order to understand the status of these, it is often necessary to examine first category and see what falls outside of this.

The same type of categorization can be made regarding the Caregivers tied to these remedies. There are those that are respected, the licensed medical practitioners; those that are tolerated; the therapists; and finally those that are not tolerated at all in today’s medicinal world.

## 1.1.2. Purpose

The general purpose of this thesis is to examine whether the Swedish attitude towards Complementary medicines is defensible within a European perspective. This can be further divided into three parts:

- To research the historical aspects of the development of Complementary medicines and to understand *why* the legal situation is what it is today;
- To explore the legal situation and current Swedish law regarding complementary remedies, and the attitudes towards it; and finally

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<sup>1</sup> Dorland, W., *Dorland’s Illustrated Medical Dictionary*, Edition 28, WB Saunders Company, Philadelphia 1994.

<sup>2</sup> SOU 2004:123, *Ett nationellt register över yrkesutövare av alternativ eller komplementärmedicin*, page 39.

- To compare the Swedish position to the EU legislation and other Member States' national legislations in use today.

The connecting thought that will run through all three sections will be the expression *quackery* as it has been used through the centuries. I will implicitly be investigating which types of remedies have been seen as quackery through the ages and whether these attitudes have changed or will have to change because of the general cultural impact from neighbouring countries and the Swedish entry into the European Union.

### 1.1.3. Method

The method used in the initial chapter will be *the historical method*. This means putting the legal situation and the judicial enactments of today in a *context*, without which the law becomes a merely technical phenomenon.<sup>3</sup> I will mainly refer to literary and legislative sources and try to categorize views concerning Complementary medicines in terms of generally accepted historical periodisation. I will briefly summarise the historical facts and events occurring between ancient times and today's Post-modern situation and try to explain developments regarding Complementary remedies in the light of these facts and in a diachronic manner.

I will then move on to a *traditional legal method* as I explore the Swedish and European legal situation as it is today. This will be done synchronically, by examining law, cases and doctrine applicable to the purpose of the thesis.

I will conclude by using a *comparative method*, meaning that I will be comparing Swedish legislation and attitudes towards Complementary remedies to those of other European countries and exploring the reasons for the differences, if any.

### 1.1.4. Material / Research situation

The main source of information for the first part of my thesis will be historical publications, both in the sense of those *written* at different historical times and *contemporary* historical literature. Examples of the latter are "*Medicinens öga*" by Karin Johannisson<sup>4</sup>, professor of idé och lärdomshistoria at Uppsala University, and *The greatest benefit to mankind; a medical history of humanity from antiquity to the present*, by historian Roy Porter<sup>5</sup>. I will be examining historical legislation and case-law when available and applicable. It should be noted that legal doctrine on the subject is scarce.

In the second part, rules and regulations in force in Sweden and directives and legal acts of the European Union will be the primary sources, as well as case-law and doctrine discussing these enactments. Also with respect to recent development it is difficult to find legal writing on the subject. I have to some extent relied on the Swedish Government Official Report *SOU 2004:123, Ett nationellt register över yrkesutövare av alternativ eller komplementärmedicin*.

<sup>3</sup> Modéer, K.Å., *Det nära förflutna; Rättskulturer i förändring*, Läromedel i rättshistoria, Juridiska institutionen, Lund 2004, page 9.

<sup>4</sup> Johannisson, K., *Medicinens Öga*, ePan, Stockholm 1990.

<sup>5</sup> Porter, R., *The greatest benefit to mankind, a medical history of humanity from antiquity to the present*, HarperCollins Publishers, London 1997.

### 1.1.5. Delimitations

Bearing in mind the limited length of this thesis, not all Complementary medicinal products or methods can be discussed; the focus will therefore be on two of them: Natural remedies and Homeopathic products and methods. I shall try to follow the development of attitudes towards these products and towards the main figures tied to them in the course of history, though I will also touch on other products throughout the paper.

Events occurring before modern times will be discussed with the utmost brevity in the historical part of the paper.

This thesis will not be concerned with exploring in any great detail the history of Complementary medicines in countries other than Sweden. However, a comparative section regarding the current situation in other countries is of interest in helping me to reflect in my Analysis on the defensibility of the situation in Sweden.

### 1.1.6. Definitions

#### *Products and methods*

*Medicinal products*: products which are intended for administration to human beings or animals in order to prevent, detect, palliate or cure disease or symptoms of disease or to be used for a similar purpose.<sup>6</sup>

*Conventional medicine*: the science and the medicinal methods taught in Sweden in State colleges and university, which is based on Science and Verified Experience.<sup>7</sup>

*Complementary medicines*: method falling outside of Conventional medicine, a medicine, which, unlike the Conventional medicine is *not* based on Science and Verified Experience. In this thesis, I will not make a distinction between alternative and Complementary medicines, unless specified, but instead I wish to use the term simply as a contrast to Conventional medicine. With regards to the term Complementary medicines, these consist of an extremely large number of different medicinal methods, and the expression is very dynamic. It can change to include or exclude any methods depending on the time period in question.

*Acupuncture*: (from Latin *acus*: a point + *pungere*: to prick<sup>8</sup>) the Chinese practice of insertion of needles into specific exterior body locations to relieve pain, to induce surgical anaesthesia, and for therapeutic purposes.<sup>9</sup>

*Naprapathy*: (from Czech *napravít*: to correct + Greek *pathos*: suffering<sup>10</sup>) a system of therapy employing manipulation of connective tissues (ligaments, muscles, and joints) and dietary measures; said to facilitate the recuperative and regenerative processes of the body.<sup>11</sup>

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<sup>6</sup> [http://www.mpa.se/eng/medical\\_products/natural\\_remedies/index.shtml](http://www.mpa.se/eng/medical_products/natural_remedies/index.shtml), (February 2005).

<sup>7</sup> <http://www.smarta.nu/ordbok/default.asp>, (February 2005).

<sup>8</sup> Angel, G. (red.), *Fakta och röster om alternativ medicin; en delrapport från alternativmedicinkommittén*, Allmänna Förlaget, Stockholm 1987, page 207.

<sup>9</sup> Dorland, W., *Dorland's Illustrated Medical Dictionary*, supra 1.

<sup>10</sup> Angel, G. (red.), *Fakta och röster om alternativ medicin*, supra 8, page 203.

<sup>11</sup> Dorland, W., *Dorland's Illustrated Medical Dictionary*, supra 1.



*Zonetherapy*: (also known as reflexology) the treatment of a zone system (a limited part of the body, for example feet, ears, teeth) which are believed to reflect the entire body. The method is used to locate problem areas as well as for treatment of disorders.<sup>12</sup>

*Natural remedy*: Medicinal product in which the active ingredient or ingredients derive from natural sources, have not been processed too highly and consist of part of a plant or animal, bacterial culture, mineral, salt or salt solution. Natural remedies (in Sweden) are products which are suitable for self-medication in accordance with tested national tradition or the tradition in countries close to Sweden with respect to drug usage.<sup>13</sup>

*Homeopathic product*: Medicinal product prepared from homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the individual countries.<sup>14</sup> Homoeopathic products may contain single stocks or a number of stocks. The latter are called complexes.

*Non-tolerable remedies*: remedies falling outside of the tolerated complementary methods in any given county; remedies which are not accepted in a given society.

### **Actors**

*Licensed practitioner*: those that are licensed and use one of the protected professional titles listed in LYHS's third chapter, namely: (1)pharmacist, (2)occupational therapist, (3)midwife, (4)chiropractor, (5)speech therapist, (6)doctor, (7)naprapath, (8)optician, (9)psychologist, (10)psychotherapist, (11)dispenser, (12)x-ray nurse, (13)physiotherapist, (14)hospital physicist, (15)nurse, (16)dental hygienist, (17)dentist.

*Paramedicinal practitioner*: health care providers not falling under any of the previously mentioned categories; those who commercially examine another's health situation or treat another for illness by measures taken or prescribed with the purpose of preventing, curing or alleviating illness.<sup>15</sup>

*Protected Professional Title*: titles of the professions listed in LYHS 3:2<sup>16</sup>. The professional titles may be used only by those who have a licence or have gone through the prescribed practical duties.<sup>17</sup>

*Health Care Personnel*: professionals that are licensed or use a protected professional title and those who take part in the care of patients in hospitals and other care facilities, or who assist licensed professionals, as well as apothecaries, emergency line personnel, groups of professionals included by specific instructions and foreign Licensed practitioners.

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<sup>12</sup> SOU 1989:60, *Huvudbetänkande från alternativmedicinkommittén*, Stockholm 1989, page 185.

<sup>13</sup> [http://www.mpa.se/eng/medical\\_products/natural\\_remedies/index.shtml](http://www.mpa.se/eng/medical_products/natural_remedies/index.shtml), (February 2005).

<sup>14</sup> Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. OJ L 136, 30/04/2004 P. 0034 – 0057, Article 1 (2) (subparagraph 1).

<sup>15</sup> LYHS, 4:1.

<sup>16</sup> LYHS, below note 256, 3:2.

<sup>17</sup> Id., 3:5

*Caregivers*: those who commercially examine a patient's health situation or provide treatment for illness by measures taken or prescribed with the purpose of preventing, curing or alleviating illness, irrespective of education and license.

*Science and Verified Experience*: key term used to enable one to distinguish between Conventional medicine and Complementary medicine in Swedish law.

*Medical care*: must have as its purpose the diagnosis, treatment, and, as far as possible, cure of diseases or health disorders.<sup>18</sup> The term "medical care" does not call for an especially narrow interpretation,<sup>19</sup> and covers all provision of medical care including services provided by persons who are not doctors, but who provide paramedical services.

*Quack*: one who fraudulently misrepresents his ability and experience in the diagnosis and treatment of disease or the effects to be achieved by the treatment he offers.<sup>20</sup>

### 1.1.7. Outline

This thesis is divided into three main sections and a conclusion. The first section will deal with the historical aspects of Complementary medicines. I will explore what was considered quackery and Conventional medicine respectively in different eras. The historical examination will span a long time period, that between ancient times and today, but with a particular focus on the recent past. This section will provide a general understanding of the historical background to the legal situation. The second section will scrutinize the use and legal control of these remedies in both Sweden and the European Union. I will compare and contrast the European legal enactments with the Swedish. In section three, my earlier findings will be analyzed and discussed. I will conclude with my personal reflections and suggestions.

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<sup>18</sup> Case C-45/01, below note 202, paragraph 48.

<sup>19</sup> *Id.*, paragraph 49.

<sup>20</sup> Dorland, W., *Dorland's Illustrated Medical Dictionary*, supra 1.

## 2. The History of Medicines

Our contemporary view of chronology can be said to see it as having a structure built on three successive knowledge paradigms: pre-modern times, the modernist 20<sup>th</sup> century and the post-modernist 21<sup>st</sup> century, though these eras overlap and certainly do not change with the change of the centuries. In fact all three can be seen in the 20<sup>th</sup> century. The three knowledge paradigms can be seen in the great German 19<sup>th</sup> century philosopher Hegel's construction, which would regard the Idealistic 19<sup>th</sup> century structure as the thesis and the pragmatic, modern 20<sup>th</sup> century as the antithesis.<sup>21</sup> For a few decades we have been in a creative and dynamic time period which can only be described as the synthesis, where we are returning to the past to create the future. In order for one era to understand another, it must be admitted that the passing of time has changed both living conditions and human mentality.<sup>22</sup>

### **2.1. Pre-modernism – a European perspective on medicinal tradition**

Pre-modernism, more than anything, is a term used to contrast with events occurring in the modernist times. It can be seen as a way to define more clearly what modernism implies. It is therefore difficult to define pre-modern times as a certain time span. It is instead useful to look at those events occurring before the rise of modernism that are characteristically different from typically modern events. All events occurring before modernism can be treated in the pre-modernism section, though it is important to keep in mind that this division is overbroad, as it spans many centuries, going all the way back to ancient times. These will be treated summarily, due to both limited historical sources and limited size format of this paper. It can be of interest, since as long as there has been illness, man has been trying to cure it. The pre-modernist section will then be further divided up into sections, in order to make it more accessible.

As the sources are limited, part of this section will have a more international character in order to establish general attitudes towards medicine and its actors in the different eras. Also, all aspects of medicine and all Caregivers will be explored, as the division of medicine into scientific/complementary is a recent one.

#### **2.1.1. Ancient times**

Man first sought to find cures to illness in nature, mostly in the plant/floral kingdom. The medicine man was the doctor, the priest and the magician of the tribe. His cures included natural remedies and rituals to drive away demons and please the Gods, since these were thought to have caused the disease in the first place. Many plants used in different parts of the world for thousands of years are still used today.

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<sup>21</sup> Modéer, K.Å., *Det nära förflutna*, supra 3, page 193.

<sup>22</sup> Tosh, J., *Historisk teori och metod*, Studentlitteratur, Lund 1994, page 23.

The Sumerians, inhabitants of the areas around the rivers Euphrates and Tigris around 4000 B.C. are known to have used opium and thyme as medication. Cuneiform writing on clay tablets describes these and other drugs.<sup>23</sup> The Sumerian culture and their knowledge of medicine was passed on to the Babylonians and Assyrians and the Babylonian king Hammurabi instituted laws which included medical regulations. The code of Hammurabi applied the principles of compensation and retribution in kind: if a slave died while under medical treatment, the practitioner had to provide a replacement, whereas if the deceased were not a slave, the doctor was to lose a hand.<sup>24</sup> In addition to the drugs used by the Sumerians, coriander, cinnamon, garlic and saffron were used, and were prepared as decoctions, medicinal wines, liniments and creams.<sup>25</sup> Medicine was not presumed to be connected to religion only, but also to astronomy.

Our understanding of Egyptian medicine and pharmacology is based on inscriptions on monuments and graves and papyrus rolls, the most important one being Papyrus Ebers<sup>26</sup>. It is thought to have been written around 1550 B.C. and includes some 800 recipes and lists 700 native and foreign drugs, including aloe, wormwood and peppermint. These were prepared as decoctions, pills, creams and patches. Recipes for incense for temples, cosmetics and perfumes can also be found. It is, however, difficult to identify the drugs described in Papyrus Ebers, since these have been given code names in order not to disclose the priests' secrets. Medicine was practiced by priests who concocted drugs in special rooms in the temples.<sup>27</sup> The Egyptians exported many medicinal plants that they cultivated, and they had some trade with foreign countries. Most importantly, it was the maritime Phoenicians that conducted trade in the products of the east and the south, and in their port Tyre, a flow of drugs from Mesopotamia, Arabia, China, India and the Mediterranean countries flourished. Another important commerce route was by land between China and India, and then through to Arabia.

### 2.1.1.1. The Greek and Roman medicinal evolution

In Greek culture, medicine was also practiced by priests. Offerings were made to Asklepios, who was the God of Medicine, and temples were built in his honour to which ill people came to be cured. Doctors provided expert opinions in trial proceedings, although such evidence was not required by law.<sup>28</sup>

Greek medicine prospered around 500 BC, its most prominent representative being Hippocrates (c. 460-377 BC), the founding father of medicinal science. All we know of Hippocrates is legend. The methods used by Hippocrates are preserved in a group of medical treatises known collectively as the Hippocratic Corpus,

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<sup>23</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, Readers Digest AB, Stockholm 2001, page 13.

<sup>24</sup> Crawford, C., *Medicine and the law*, Chapter 69 in volume 2 of Companion Encyclopaedia of the History of Medicine, Edited by Bynum, W.F., and Porter, R., Routledge, London & New York 1993, page 1620.

<sup>25</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 14.

<sup>26</sup> Named after the German Egyptologist Georg Ebers, professor in Leipzig, who bought the papyrus roll 1872 in Luxor, Egypt from an Arab who claimed to have found it between the knees of a mummy found outside of the city of Thebe.

<sup>27</sup> Porter, R., *The greatest benefit to mankind*, supra 5, page 47.

<sup>28</sup> Amundsen, D., and Ferngren, G., *The physician as expert witness in Athenian law* in Bulletin of the History of Medicine, No 51 1977, page 202-13.

“Corpus Hippocratum”. It is a compilation of 70 documents put together about 100 years after his death. He held the belief that illness had a physical and a rational explanation, thereby rejecting the views of his time that considered illness to be caused by possession of evil spirits or the disfavour of the gods. His greatest contribution was that he regarded medicine as scientific.<sup>29</sup>

The principle idea of his work is *Primum est non nocere*, that is to say *The most important is not to harm*.<sup>30</sup> Grounded on the Empedoclean principle of the four supposed elements: earth, air, fire and water, the four constituent elements - or humours - in man were identified analogously as phlegm, blood, yellow bile and black bile, all of which had to be in correct proportion to one another. The elaborate general doctrine of the Four Humours endured through many centuries and is central to the tenets of the Hippocratic Corpus. Though virtually worthless as a theory, it remained the fundamental prop of European medicine for over two millennia.<sup>31</sup>

*Theriaca Adromachi*, a compounded pharmaceutical created by the medical practitioner Andromachus of Crete in the first century AD, played an important role in Europe for more than 1500 years as an unrivalled universal drug.<sup>32</sup> It contained many medicinal plants, oriental spices and balms, but also medicinal animal parts – snake flesh for example. The addition of this was typical of the way of thought of the era: it was supposedly an excellent cure against snake bites, but also, it had a symbolic meaning tied to Asklepios, God of Medicine, who used a snake in his remedies. The need for snake flesh for *Theriaca* was great, and the hunt for vipers was undertaken by special snake hunters. In the Middle Ages, these hunters belonged to specific guilds with their own decrees/ordinances in certain areas! A recipe for *Theriaca* can be found in Sweden’s first pharmacopoeia of 1686. It is a composition of 66 ingredients, including cinnamon, saffron, pepper, Venetian turpentine, ginger, opium and drugs originating from fauna such as Italian snakes and glandular secretion from beavers. However, through the new Medicinal enactment (*giftstadga*) of 1876, which prohibited the use of opium in *Theriaca* concoctions, its use decreased in Sweden and came to an end at the turn of the century.<sup>33</sup>

In 146 BC, Greece came under Roman supremacy. The Romans themselves had little interest in medicine, and this continued to be dominated by the Greek scholars. The Roman warriors treated illness with simple methods relying on the Gods through prayer and offerings. Of course, the doctors accompanying the Roman legions on their crusades were given important practical experience with surgical operations. It became the norm to have a Greek slave, knowledgeable in medicine in the rich patrician households, a “*servus medicus*”.

In the second century AD in Rome lived Claudios Galenos, a doctor whose teachings would mark medicinal science for more than a millennia. He further elaborated Hippocrates’ teachings on humoral pathology and the restoration of their balance with the use of medication. His ideas and the recipes for the concoctions were spread across the known world and it was thought that this was the goal of human medicinal art fulfilled. Through Arabic and Hebrew translations, his work survived the migrations. During the Medieval era, his teachings were the source of all medicinal knowledge.<sup>34</sup>

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<sup>29</sup> Porter, R., *The greatest benefit to mankind* supra 5, page 55.

<sup>30</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 16.

<sup>31</sup> Porter, R., *The greatest benefit to mankind* supra 5, page 5.

<sup>32</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 18.

<sup>33</sup> Id., page 18 - 19.

<sup>34</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 22.

### 2.1.1.2. Medieval Europe

Medical knowledge developed slowly in the Middle Ages. While the Ancient Romans, Greeks and Egyptians had pushed forward medical knowledge, after the demise of these civilisations, the momentum started by these people tended to stagnate and it did not develop at the same pace until the seventeenth/eighteenth centuries. However, the growth of towns in medieval Europe was accompanied by an increase in both the regulation of medicine and the policing of crime.<sup>35</sup> The idea was to suppress private vengeance and to facilitate redress through law instead.

From the Middle Ages, medical practitioners organized themselves professionally in a pyramid with physicians at the top and surgeons and apothecaries nearer the base, with other healers marginalized or seen as quacks.<sup>36</sup>

By the 14<sup>th</sup> Century, universities that could be classed as medical schools had developed in Western Europe; there students could study under a master physician. The University of Montpellier was one such university. Dissections of human bodies were carried out in these universities so anyone wanting to study medicine in the Middle Ages was not totally ignorant of facts about the human body. Public debates were also encouraged about medical issues and it is known that some medical schools encouraged students actually to challenge the ideas of Galenos and Hippocrates.<sup>37</sup> As a result of this refusal to take what Galenos and Hippocrates had stated at face value some progress was made in the medical world.

However, medicine became steeped in superstition and the Roman Catholic Church effectively dominated the direction the medical world took.<sup>38</sup> Any views different from the established Roman Catholic Church view could veer towards heresy with the punishments that entailed. Therefore, when the Roman Catholic Church stated that illnesses were punishments from God and that those who were ill were so because they were sinners, few argued otherwise.

#### *The Monasteries*

In early medieval times, the monastery system spread throughout Europe through different monastic orders. The monks copied medical authors from antiquity and translated Arabic documents into Latin.<sup>39</sup> They practiced healthcare influenced both by Graeco-Roman medicine and Arabic treatments. Even popular medicine was used and the monks had considerable practical experience. Many monasteries had specific buildings used for caring for the ill and the novices were taught medicinal subjects in the monastery schools. Medicinal plants were cultivated in the gardens of the monasteries.<sup>40</sup>

#### *Witchcraft<sup>41</sup>*

Few crimes have been given as much attention by legal-historical or historical research as the witch hunts in Europe. From the early 1400s to the early 1700s, men and - primarily - women were judged and executed for crimes, which we today

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<sup>35</sup> Crawford, C., *Medicine and the law*, supra 24, page 22.

<sup>36</sup> Porter, R., *The greatest benefit to mankind*, supra 5, page 11.

<sup>37</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 26.

<sup>38</sup> Porter, R., *The greatest benefit to mankind*, supra 5, page 11.

<sup>39</sup> [http://www.historylearningsite.co.uk/history\\_of\\_medicine.htm](http://www.historylearningsite.co.uk/history_of_medicine.htm), (August 2005).

<sup>40</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 24.

<sup>41</sup> Häthén, C., *Stat och straff, Rättshistoriska perspektiv*, Studentlitteratur, Lund 2004, page 76.

regard as imaginary. In many cases, the defendants were guilty only of concocting medications – what we would call practicing Complementary medicine today. Witches and sorcerers were thought to be close to a natural magic, and in an agrarian society, their special knowledge was often used. Around 1500, a handbook of witch hunting – *Malleus Maleficarum* – was written by two monks. This led to spectacular executions, with the alleged criminals being burnt at the stake or drowned in public.

All the Swedish medieval laws, Lanskapslagarna and Landslagen, treated the subject of witchery. The punishment was death.<sup>42</sup> Witchery was a serious crime, a religious crime. In the 16<sup>th</sup> and 17<sup>th</sup> century, activities such as gathering healing herbs in the moonlight were very likely to lead to the death penalty. In Sweden, the first known witchery processes occurred again around 1500.<sup>43</sup>

Witch hunting had almost completely ended before the coming into force of the new Swedish Law of 1734, though it was still a punishable crime in the law.<sup>44</sup> The then king (Gustav III), however, proposed its removal in 1778, and Parliament supported the motion.<sup>45</sup>

### 2.1.1.3. The Antique Art of Medicine is Challenged

The first man - after 14 centuries! - to challenge the theories of Hippocrates and Galenos, was the Swiss doctor and philosopher Philippus Aurelius Theophrastus Bombastus von Hohenheim.<sup>46</sup> He was critical of classical medicine's representatives and provoked an enormous academic debate with his colleagues. Paracelsus burned Hippocrates' and Galenos' works and lectured in German instead of academic Latin. In his struggle to ameliorate the art of medicine he gained knowledge from medieval alchemy and introduced chemical medicines, whose "quintessence" was to give them medicinal value.<sup>47</sup>

After Paracelsus' death, the battle between the followers of Galenos' medicinal views and the advocates for the new ideas that Paracelsus brought forth continued.

The *signature doctrine* developed and held that nature itself always gave mankind a clue as to how her gifts should be used. The world was a pharmacy and God its apothecary. Paracelsus was amongst the most ardent supporters of this theory. Herbs with spherical flowers cured head aches, and those with kidney shaped leaves cured kidney diseases. Flowers shaped as eyes cured ophthalmic diseases and winding, serpentine plants snake bites. The idea was *Simila similibus curantur*, i.e. likes cure likes.<sup>48</sup> This idea has been inherited by the homeopathic movement.

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<sup>42</sup> See for example Östgötalagen, Vådamålsbalken XXXI, §1, in Häthén, C., & Nilsén, P., *Svensk historisk lagbok* Studentlitteratur, Lund 2004, page 27: *Nu tillvitas en kvinna trolldom, och hon blir tagen på bar gärning, och det blir sturkt med säkra vittnen; då har hon förverkat sitt live, och henne skall man stena ihjäl.* Roughly translated: *If a woman is caught practicing witchery and this is confirmed by witnesses, she has forfeited her right to live and is to be stoned to death.*

<sup>43</sup> Häthén, C., *Stat och straff*, supra 41, page 109.

<sup>44</sup> 1734 års lag, Missgärningsbalk, II Kap. Om trolldom och vidskepelse, 1§, in Häthén C., & Nilsén, P., *Svensk historisk lagbok*, supra 42, page 132.

<sup>45</sup> Häthén, C., *Stat och straff*, supra 41, page 167.

<sup>46</sup> Born in 1493, he took the name Paracelsus after graduating as a doctor from the university of Ferrara, according to Porter, R., *The greatest benefit to mankind* supra 5, page 201.

<sup>47</sup> Id., page 25.

<sup>48</sup> [www.homeopathic.org](http://www.homeopathic.org), (August 2005).

## 2.1.2. From Reformation to Revolution

### 2.1.2.1. Reformation

It is here, in the 16<sup>th</sup> century, that we begin to see a dichotomy between Conventional medicine and Complementary medicine. Before this time they had been effectively the same, and during this period and for a long time thereafter they continued to evolve in parallel.<sup>49</sup>

Before the Swedish Reformation, which occurred in the 1520s, Swedish society was by and large agrarian<sup>50</sup> making the distance between doctors considerable. Healthcare was traditionally a family affair, and should anyone else be involved, it was the church. It was not until the 17<sup>th</sup> century that there was any attempt in Sweden to organize medicine on a national level and it would not be until the second half of the 18<sup>th</sup> century before the family physician started to appear in the cities.<sup>51</sup> With the reformation and the change of the church's role, the Crown's interest in healthcare did expand.<sup>52</sup>

Religion strongly influenced developments during this period.<sup>53</sup> When Sweden abandoned Catholicism in the 16<sup>th</sup> century and became Lutheran, the monasteries were shut down and so was the monks' medical work. There was a demand for freedom from the priests' supremacy, and from the tyranny of the Catholic church.<sup>54</sup> During the next few centuries, it was instead the Lutheran priests who came to act as medical practitioners and who improved public health in Sweden.<sup>55</sup> When the peasantry fell ill, they consulted the traditional "wise" men and women, and when these didn't have solution, priests were asked for help; thus not only with spiritual but also bodily problems.<sup>56</sup> The church and its representatives existed throughout the country. The priests worked in a very close relation with the public, and knew all the members of their congregation/parish.<sup>57</sup> Often, the priest was the only one in the district with any higher education. It was therefore understandable that the priests' medical effort/contribution was tolerated and even encouraged by the public authorities.

Peasantry also put their trust in other healers. Foreign frauds marketed their wonder drugs and miracle remedies to a gullible and distressed general public. These universal drugs sold by these quacks could be used for anything ranging from plague to cholera.<sup>58</sup>

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<sup>49</sup> Johannisson, K., *Medicinens öga*, supra 4, page 35.

<sup>50</sup> Behre, G., Larsson, L-O., & Österberg, E., *Sveriges historia 1521 – 1809*, Liber AB, Stockholm, 2001, page 27.

<sup>51</sup> Johannisson, K., *Medicinens öga*, supra 4, page 33.

<sup>52</sup> Nelson, M.C., *En historia om vård förr in Perspektiv på komplementär Medicin*, red. Eklöf, M., 2004 Studentlitteratur, page 37.

<sup>53</sup> Häthén, C., *Stat och straff*, supra 41, page 53.

<sup>54</sup> Id., page 59.

<sup>55</sup> Bergström, C., *Lantprästen; Prästens funktion i det agrara samhället 1720 – 1800*, Nordiska museet, Stockholm 1991.

<sup>56</sup> Engman, S., *Läkekunst och Kvacksalveri – ett konfliktområde*, Strömsund 1990, page 8.

<sup>57</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 36.

<sup>58</sup> Id., page 37.



### 2.1.2.2. The Great Power Era

During the 1600s, Sweden came to play a more active and dominant role in Europe than at any time before or after. Sweden became a Great Power in many senses. In foreign politics and in military aspects, economically and administratively, Sweden was equal to - if not superior to - other European countries.<sup>59</sup> The personal royal power was given a large span of interpretation, and the nobility had expanded privileges in the form of a preferential right to higher offices, and economical reliefs.<sup>60</sup> However, Sweden was at the time going through some internal difficulties, especially with regard to the Crown's financial situation, and centralised bureaucracy greatly expanded during this time in order to control the problems.<sup>61</sup>

In 1663, four licensed practitioners created the *Collegium Medicum*, a private society – a guild set up by the physicians themselves. Their mission was to organise the whole medical system.<sup>62</sup> Education in internal medicine had been organised in the mid-century, but was so unsatisfactory that it was necessary to have a foreign diploma in order to be accepted as a licensed medical practitioner.<sup>63</sup>

As a result of the medicinal ordinances of 1688, the formerly private society became public and official. With the increase in mercantilist<sup>64</sup> thinking, the interest of the state in population questions increased, and with this, an interest in medicine as well. The strength of the state was defined as the access to capital, and manpower was the most important capital producing resource.<sup>65</sup> Therefore, medicine had to ensure the greatest number of healthy workers possible. The Collegium Medicum had the responsibility for supervision of doctors, pharmacists, midwives and barbers, and for preventing quackery - defined in accordance with the monopoly given in the medicinal ordinances, that is to say that anyone acting outside of this monopoly was regarded as a quack. However, Collegium Medicum lacked real power.<sup>66</sup>

The 1688 Medicinal enactments<sup>67</sup> regulated the Collegium Medicum's activities and authorities. It also contained prohibitions on pharmacists practicing as doctors and spice dealers<sup>68</sup> selling pharmaceuticals. It thus constituted a complete monopoly in the field of medicine, though this, as we will see, was not followed in reality. This law was not replaced officially until 1915, more than 225 years later.

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<sup>59</sup> Behre, G., et al., *Sveriges historia 1521 – 1809*, supra 50, page 74.

<sup>60</sup> Id., page 86.

<sup>61</sup> Id., page 87.

<sup>62</sup> Nelson, M.C., *En historia om vård förr*, supra 52, page 37.

<sup>63</sup> Id., page 37.

<sup>64</sup> *Mercantilism*: the dominating economical system during the 18<sup>th</sup> century, which held that exports should exceed imports, domestic production should be encouraged, believed in economical regulations and protectionism and stressed what was important and useful for the State, according to Behre, G., et al., *Sveriges historia 1521 – 1809*, supra 50, page 253.

<sup>65</sup> Johannisson, K., *Medicinens öga*, supra 4, page 45.

<sup>66</sup> Rogers, J., *Hälsovårdsutvecklingen i Sverige under den epidemiologiska transitionen: En jämförelse med England och Tyskland*, Sydsvenska medicinhistoriska sällskapets årsskrift, s. 103 - 117, 1990.

<sup>67</sup> Kungl. Maj:ts Medicinalförordningar av den 30 oktober 1688.

<sup>68</sup> *Kryddkrämare*, translation found on [www.ddss.nu/ordbok](http://www.ddss.nu/ordbok) (August 2005). Spice dealers were only allowed to sell dry goods such as coffee, flour, sugar and also things such as china, buttons and newspapers.

In 1686, Sweden's first pharmacopoeia was published – “Pharmacopoeja Holmiensis galeno-chymica”, which included a chapter describing chemical medicines.<sup>69</sup> Though first intended as a pharmacopoeia only for apothecaries in Stockholm, Karl XI gave it a national status.<sup>70</sup> The pharmacopoeia was the result of work done by the Collegium Medicum.

At the end of the Great Power era, there were four Swedish Universities; Uppsala, Lund, Åbo and Greifswald. These were originally what can only be characterised as seminaries, but as a result of Enlightenment ideals, a secularisation process took place.<sup>71</sup> Science became increasingly important, and with this, the science of medicine as well. Medical faculties were inaugurated between 1640 and 1666 at each of the four Universities.<sup>72</sup>

The eighteenth century was a century of enormous change. European thought became overwhelmingly mechanistic as the natural philosophy of Isaac Newton was applied to individual, social, political, and economic life.<sup>73</sup> The century saw the development of the *philosophe* movement,<sup>74</sup> which articulated the full values of the European Enlightenment, including deism, religious tolerance, and political and economic theories that would dramatically change the face of European society. Europe itself changed from a household economy to an industrial economy.<sup>75</sup> This change, perhaps one of the most earth-shattering transitions in human history, permanently altered the face of European society and family life. Finally, the century ended in revolution. The ideas of the *philosophes* were translated into new governments - one in France and one in America.

### 2.1.2.3. Enlightenment

As a historical category, the term “Enlightenment” refers to a series of changes in European thought. It is one of the few historical categories that was coined by the people who lived through the era (most historical categories, such as “Renaissance”, “Early Modern,” “Reformation,” etc., are made up by historians after the fact).<sup>76</sup> When contemporary people referred to their activities as “Enlightened”, they meant that they were breaking from the past and replacing the darkness and ignorance of European thought with the light of truth.

The period was filled with optimism and a strong belief in rationally changing society, to get rid of the old and replace it with the new (Voltaire). It is important to point out that it is during the Enlightenment that religion's dominating role was phased out. As a result, purely religious crimes, such as witchcraft, were removed from the penal code.<sup>77</sup> Mercantilism<sup>78</sup> continued to be an important economic political theory for a large part of the century.

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<sup>69</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 26.

<sup>70</sup> Id., page 27.

<sup>71</sup> Behre, G., et al., *Sveriges historia 1521 – 1809*, supra 50, page 213.

<sup>72</sup> <http://www.susning.nu/Universitet> (August 2005) The medical faculty at Lund University was inaugurated in 1666, in Uppsala 1660, in Åbo 1640, no information on Greifswalds Medicinal faculty.

<sup>73</sup> <http://www.wsu.edu/%7Edee/ENLIGHT/ENLIGHT.HTM> (August 2005).

<sup>74</sup> Id.

<sup>75</sup> Outram, D., *The Enlightenment*, Cambridge University Press, Cambridge 1995, page 75

<sup>76</sup> <http://www.wsu.edu/%7Edee/ENLIGHT/ENLIGHT.HTM> (August 2005).

<sup>77</sup> Häthén, C., *Stat och straff*, supra 41, page 170.

<sup>78</sup> supra 64.

The “scientific<sup>79</sup> revolution”, associated with natural science and technological change, swept across Europe.<sup>80</sup> In reality the scientific revolution affected the structure of European thought itself; systematic doubt, empirical and sensory verification and the partition of valid human knowledge into separate sciences all arose.<sup>81</sup> Empirical research principles were also used during the enlightenment period. The scientific, utilitarian and empirical ideas so developing were steadily exported to the human sciences. In theories of personality, human development, and social mechanics, 17<sup>th</sup> century thinkers moved away from religious and moral explanations of human behaviour and towards an empirical analysis and mechanistic explanation of the laws of human behaviour.<sup>82</sup>

However, Enlightenment medicinal science suffered from the apparent paradox of great expectations, but disappointing results. Medicine failed to match the achievements of experimental physics or chemistry, even though numerous medical authors sought to set their discipline on scientific rails.<sup>83</sup>

In the public’s opinion, the doctors were not regarded as having a monopoly on the knowledge of medicine until after 1870.<sup>84</sup> The fact that the Medicinal Act of 1688 had supported and favoured doctors over other Caregivers’ expense was a Swedish deviation from the European development, but it is questionable to what degree it had really been put into practice. The legal framework controlled unauthorised healers and gave precedence to licensed, university educated physicians. The Medical Act confirmed the physicians’ exclusive right to practice internal medicine. The royal decrees were not motivated by an urge to protect the public from harm, but to safeguard groups of qualified professionals and their ability to earn a living.<sup>85</sup>

Well into 18<sup>th</sup> century Sweden, Conventional medicinal remedies were dominated by drastic methods of treatment such as blood-letting, emetics, strong laxatives and such. This was a reminiscence of the humour pathology’s theories of the bodily fluids.<sup>86</sup>

In parallel, unlicensed healers combined superstition and a real knowledge of herbal remedies.

One of the most commonly hired healers in the mid 1700s was Sven in Bragnum, who not only cured people and animals in his own area but from neighbouring provinces and even Norway and Denmark. Ill people from all social classes sought his help. Carl von Linné met him on his well documented trip to Västergötland. He found him to lack self-insight, but he was to be commended for not relying on superstitions and being accommodating with payment.<sup>87</sup>

Maria Jansson, known under the name of Kisa-mor, is one of the best known natural medicinal practitioners of the first half of the 1800s. Her remedies were simple herbal preparations. The reputation of her wonder-working spread and in 1824 she was called to Stockholm to try curing an important person, in which she succeeded. Soon all of Society’s

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<sup>79</sup> It is important to bear in mind that the in using the word “science” we are committing the sin of anachronism, since the word was not invented until the 1830s.

<sup>80</sup> <http://www.wsu.edu/%7Eede/ENLIGHT/ENLIGHT.HTM> (August 2005).

<sup>81</sup> Outram, D., *The Enlightenment*, supra 75, page 3.

<sup>82</sup> Id., page 15.

<sup>83</sup> Porter, R., *The greatest benefit to mankind* supra 5, page 248.

<sup>84</sup> Engman, S., *Läkekunst och Kvacksalveri*, supra 56, page 89.

<sup>85</sup> Johannisson, K., *Medicinens öga*, supra 4, page 35.

<sup>86</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 39.

<sup>87</sup> Id., page 38.

sick started turning to her for help. In 1825 she was rewarded an official permission by Sundhetskollegium to practice medicine – a unique reward.<sup>88</sup>

The relationship between Licensed and unlicensed practitioners was characterised by extensive antagonism, and the doctors argued forcefully against the unlicensed practitioners, seen as quacks. The doctors in the Collegium Medicum sought to thwart quackery, as illustrated by their actions in Stockholm in 1776. A survey was made of those practicing medicine and whether they were licensed or not. The Collegium wanted executive power to fine contraventions of the law. Yet these attempts to expand their powers were met with resistance, and it was found that matters of this kind were to be settled in an impartial court with the possibility of appeal. In 1797, the Collegium Medicum's authority as the organ to supervise health care increased, and it was tied to the public administration.<sup>89</sup>

In the best of societies, it was thought, the State would not be needed, but until this was the reality, the best was a strong, centralised State. It should be led by an enlightened monarch and by scientists – Enlightened despotism. The Enlightenment demanded rational laws, where all citizens were to be treated equally. Voltaire's view was that prejudices should not be allowed to govern what was criminal and he therefore acted forcefully for the secularisation of the law.<sup>90</sup>

In comparison to other European countries, it is important to bear in mind that larger structural changes came relatively late in Sweden. Industrialisation did not commence until the mid 1800s and Sweden continued to be an agrarian society with a sparse population. The availability of public health care, and its design, was naturally influenced by this.

#### 2.1.2.4. The French Medicinal Revolution

The Licensed practitioner of the 1700s was often portrayed by his contemporaries as a pompous, avaricious, uninformed person, paralyzed by prestige, but without the ability to cure.<sup>91</sup> Professional and monopolising actions during the 1780s made the Licensed practitioners appear like an incarnation of everything that made the old regime odious.<sup>92</sup>

Criticism was not merciful. Voltaire maintained that diet was far more effective than the impotent Conventional medicine, and Rousseau believed that society needed neither doctors nor hospitals.<sup>93</sup> There was a notion that the cause of disease was in society as such. Rousseau's thesis that *civilization* as such was ruining mankind's health was cogent: if the cause was in society, then it could be eliminated. If disease had societal causes, and freedom was the best societal condition, then mankind's health would be best under freedom, according to Rousseau's conception of the ideal state of things.

This period was also politically tense and - in France - economically catastrophic. There was an underlying feverish mentality, bubbling under the

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<sup>88</sup> Id., page 39.

<sup>89</sup> Ling, S., *Kärringmedicin och vetenskap*, Acta Universitatis Upsaliensis, Uppsala 2004, page 117.

<sup>90</sup> Häthén, C., *Stat och straff*, supra 41, page 121.

<sup>91</sup> Johannisson, K., *Medicinens öga*, supra 4, page 75.

<sup>92</sup> Id., page 76.

<sup>93</sup> Porter, R., *The greatest benefit to mankind* supra 5, page 76.

surface. Everything breathed of things to come. The Enlightenment's political and intellectual rationalism changed to an impatient irrationality and restlessness.

The French medicinal revolution of 1790 can be said to have been a micro cosmos corresponding to the political revolution's macro cosmos. There was unlimited optimism and desperate attempts to make the visions reality. There was a wish to break away from the old medicine. "Medicine – magnificent and sublime in its aim - is empty, wooden and practically worthless, focuses on the wrong things, is unfair, uneven, and corrupted"<sup>94</sup> according to Georges Romme speaking at the National Convention of 1793. What instead? This was formulated by Condorcet: the medicine that would be the revolution's contribution to mankind would be built on two principles. It would make health a human right. And it would be preventive rather than treatment-oriented.<sup>95</sup>

As a typical stage in any revolution, there was aggressive, destructive criticism, in this case against the medical institutions, that is to say:

- the hospitals;
- all doctoral privileges, which were wiped out in 1791;
- medical education – all public medical education at universities and academies ceased in August 1792.

Medicine belonged to citizens, not the doctors. From now on and for an entire decade to come, anyone who wished was free to *buy* a medical license.<sup>96</sup> "Officier de Santé" included anyone. This may primarily have been because of Article 6 of the French declaration of human rights, still valid today.

Law is the expression of the general will; all citizens have the right to concur personally, or through their representatives in its formation; it must be the same for all, whether it protects or punishes. All citizens being equal before it, are equally admissible to all public offices, positions, and employments, according to their capacity, and without other distinction than that of virtues and talents.<sup>97</sup>

Not at any other time in the modern history of Europe has the border between the professionals and amateurs of medicine been as wide open. In accordance with revolutionary logic, all privileged unions and associations were dissolved, including universities, medical schools and academies. Needless to say, the situation was soon chaotic. Charlatans and quacks showed up everywhere. The dream of extending equality to the field of medicine was a failure.

In 1803 a French law made all caregiving without an exam illegal.<sup>98</sup> However, medically speaking, the revolution was a success in many ways. It established that medicine was a social science and that all illness must be construed in large social contexts. Medical care's being seen as a human right was another important aspect.

### 2.1.3. A century of Political and Industrial influences

Overall, the end of the 18<sup>th</sup> century was characterised by a slow development from an "estate society" to one which took greater interest in "social class" - of

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<sup>94</sup> Freely translated from Johannisson, K., *Medicinens öga*, supra 4, page 72.

<sup>95</sup> Porter, R., *The greatest benefit to mankind* supra 5, page 245.

<sup>96</sup> Johannisson, K., *Medicinens öga*, supra 4, page 88.

<sup>97</sup> [http://www.thirdworldtraveler.com/Human%20Rights%20Documents/French\\_RightsofMan.html](http://www.thirdworldtraveler.com/Human%20Rights%20Documents/French_RightsofMan.html) (February 2005).

<sup>98</sup> Johannisson, K., *Medicinens öga*, supra 4, page 90.

course, things moved faster in France and in the Napoleonic Empire. It was a time where the guild system no longer prevailed and where a new middle class began to take form. The breakthrough of secularisation and the success of a capitalist society characterised this era.

### **2.1.3.1. Romanticism**

Many changes had come about in post-revolutionary Europe. However, not all of them were progressive. The age of Enlightenment in general and the French Revolution in particular gave rise to a contrasting ideal - Romanticism. It was a conservative reaction against the Great Enlightenment project.<sup>99</sup> This reaction helps identify the 1800s two political forces: *Liberalism* and *Conservatism*. Both movements sought to preserve the “ruins”, meaning they advocated evolution over revolution.<sup>100</sup>

### **2.1.3.2. Liberalism**

The liberal idea was coined around 1820 and gathered those who supported the thoughts of Enlightenment. The movement was not revolutionary, but rather favourably inclined towards reform.<sup>101</sup> The ideal of this movement was freedom - freedom *for* the individual *from* state control. In medicine this came to mean an advocacy of non-treatment.<sup>102</sup> The idea of the principle of natural order was the base of the liberal laissez-faire programme, which meant that any encroachment from the state was seen as an interference in the natural process and the individual’s personal freedom.<sup>103</sup> The state was relieved of its responsibility for the health of its citizens. Illness was seen as the result of a biological determinism, and so society could not have caused it. These thoughts fit well into the needs of Industrialism, since the illness of the workers was then the result of self-infliction and an indolent lifestyle, rather than the exploitation of them in miserable working and living conditions.

However, Liberalism called attention to many important positive arguments as to why society should not interfere. The idea of personal freedom, which was a fundamental principle, included a responsibility for ones own health. Patriarchal responsibility was to be replaced by individual responsibility. Self-help was the key word.

### **2.1.3.3. Conservatism**

Conservatism reacted to the individualism of the Enlightenment. The idea was that Man always belonged to different communities and the State was the overall, comprehensive community. The individual had duties, but no rights vis-à-vis the State.<sup>104</sup> Conservatism put tradition and verified experience first, whereas the Enlightenment had put common sense first.<sup>105</sup>

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<sup>99</sup> Modéer, K.Å., *Det nära förflutna*, supra 3, page 9.

<sup>100</sup> Id., page 30.

<sup>101</sup> Häthén, C., *Stat och straff*, supra 41, page 175.

<sup>102</sup> Johannisson, K., *Medicinens öga*, supra 4, page 62.

<sup>103</sup> Id., page 62.

<sup>104</sup> Häthén, C., *Stat och straff*, supra 41, page 175.

<sup>105</sup> Id., page 175.

The liberal idea of self-help and non-interference of society caught on in countries such as the United Kingdom and the United States, where the influence of the idea can still be seen.<sup>106</sup> In conservative Sweden, health care politics were still decided with mainly patriarchal motives and far-reaching interference from the State.<sup>107</sup> In 1813 the “Sundhetskollegium” replaced the Collegium Medicum and becomes a public authority. From the end of the 1850s the Sundhetskollegium was responsible for the Swedish health care organization.

#### **2.1.3.4. Industrialism<sup>108</sup>**

The age of industrialism meant the modernisation of Europe.

The ruling powers abandoned the idea of the individual as subordinated to the state at the end of the 1700s. The central idea is rather an expanding capitalist system in accordance with the ideas of industrialism. In this context, the individual was seen only as a basic production power. Bodies were exchangeable, and the ill were not profitable workers. The political and social development and the structure of the industrial system made it possible to maintain old medicinal control mechanisms, where the focus was loyalty to the State.

There were some private initiatives. An entire system of privately financed hospitals arose in England during the 18th century, funded by a financially strong bourgeoisie of merchants and factory owners.<sup>109</sup> These bourgeois health care contributions were a natural part of the industrialism, as the enlightenment idea of equality was changed into the bourgeoisie’s social conscience. Humanitarian efforts became virtues and private initiative compensated for society’s innate and unavoidable injustices, which can be seen as a manifestation of the pre-modernist thought of man’s given position in society.

However, these contributions were not enough to meet the problems related to industrialism. These grew, and the breach between the workers and the medicinal Establishment expanded. The average life expectancy for the middle and upper class was 36, but only 26 among the workers. The situation was a source of political unease, and anarchistic ideas formed. Friedrich Engels wrote of the proletariat’s miserable conditions and demanded radical social change. This misery and illness was political dynamite - and power paid attention. A number of health care, hygienic and social medicinal reforms were made in most western European countries in the mid 19<sup>th</sup> century.

## **2.2. Modernism – a new attitude developing in Sweden**

Modernism is a key word for understanding the events of the 20<sup>th</sup> century. It can be said that modernism identifies the modern technically advanced and functional society.<sup>110</sup> It is by definition critical towards traditions and a reaction against the 19<sup>th</sup> century’s agricultural, rural society. One can see Modernism as the Antithesis of the Pre-modernism.

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<sup>106</sup> Johannisson, K., *Medicinens öga*, supra 4, page 63.

<sup>107</sup> Id., page 64.

<sup>108</sup> This section is based on Johannisson, K., *Medicinens öga*, supra 4, page 59 – 62.

<sup>109</sup> Serafimerlasarettet, a hospital in Stockholm, opened in 1752. Engman, S., *Läkekonst och Kvacksalveri*, supra 56, page 13.

<sup>110</sup> Modéer, K.Å., *Det nära förflutna*, supra 3, page 5.

In parallel to the socio-political development during the pre-modern period, different theories regarding medicinal treatment developed and expanded.

### **2.2.1. Pluralism bordering to chaos**

Around the year 1800, there was a pluralism on the medicinal market which bordered on chaos.<sup>111</sup> Traditional medicine was being replaced by science, yet the patients were unsure of which was which.

#### **2.2.1.1. Traditional medicine**

The progressive development of medicinal science took place without changing traditional medicinal remedies. In a decreasing manner, folk medicine continued to hold a place next to the so called scholarly medicine. Folk medicine is a freer concept and included cures with herbs, not completely accepted as it was associated with magic.<sup>112</sup> Homeopathy was, and still is, often seen as folk medicine by scholarly medical practitioners, as it was not considered to be scientific. The practitioners of homeopathy, however, would not agree, and in fact would argue that their science is superior to that of Conventional medicine.

Over time, what is seen as traditional medicine is altered. When the English physician William Withering 1785 published his thesis on digitalis, it was about a plant considered folk medicine at the time. It is today one of our most important heart medications, though now it is made out of purified substances.<sup>113</sup> In the early 19<sup>th</sup> century, FWA Sertürner isolated a specific chemical subject in the opium poppy - Morphine. Chemistry kept evolving and in the end of the 19<sup>th</sup> century synthetic medications could be produced.<sup>114</sup> The science which came to specialize in the understanding of the herbal remedies came to be known as *pharmacognosia*. It evolved during the 19<sup>th</sup> century when the advanced chemical analysis instruments that we have today did not exist.<sup>115</sup>

Since the mid 1800s, the ideal of Government officials as a higher order had sprouted, and at the turn of the century, the Doctors – along with the judge, the bishop and the mayor, represented a higher order<sup>116</sup>. However, their therapeutic abilities had hardly increased. The ability to cure is what was most important in the medicinal field, not a title. This led to an enormous increase in Complementary therapies available to the public.<sup>117</sup>

#### **2.2.1.2. Homeopathy**

One of the traditional medicines to turn to was homeopathy, founded by the German doctor Samuel Hahnemann (1755-1843). He adopted the traditional idea of Signature Doctrine (see above). He had in his youth been infected with malaria and cured with China bark from the Cinchona tree. At a mature age he had reason to experiment on himself and again take a dosage of China bark and then displayed

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<sup>111</sup> Johannisson, K., *Medicinens öga*, supra 4, page, page 30.

<sup>112</sup> Loux, F., *Folk medicine in Companion encyclopaedia of the History of Medicine*, Volume 1, edited by Bynum, WF., and Porter, R., Routledge London & New York 1993.

<sup>113</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 42

<sup>114</sup> Id., page 42.

<sup>115</sup> Id., page 42.

<sup>116</sup> Johannisson, K., *Medicinens öga*, supra 4, page 38.

<sup>117</sup> Id., page 40.



symptoms similar to that of malaria. He thought himself thereby to have proven that a drug which produces symptoms which resemble a certain disease also cures that disease – *similia similibus cantur*.<sup>118</sup> This became one of the cornerstones in his doctrine, which he called homeopathy.

Between 1811 and 1821, Hahnemann was active in Leipzig, where he published his “Medicinal doctrine” and lectured about it. His reputation as a medical practitioner spread far beyond the boundaries of his home country. Hahnemann became the personal doctor of duke Ferdinand of Anhalt - Köthen and it was in Köthen that he formulated a new theory within homeopathy about the “potent” medicines.<sup>119</sup> Practically this theory meant that soluble drugs were thinned out gradually with alcohol in a ratio of 1:100 and each thinning out was done under severe shaking. The theory was that the medicines dynamic inherent power would be released through these dilutions and transfer to the dilution agent whose power would further increase with increased dilution. A dilution in the ratio of 1:100 was called the first centesimal potency, C1. Hahnemann himself used the thirtieth centesimal potency C30, which means that the original drug is diluted in enormous volumes.

### 2.2.1.3. Scientific medicine

In the 19<sup>th</sup> century, medicine developed in a scientific direction. Science became an ideal worth striving for, and the base for anything to be taken seriously. The term *Science and Verified Experience*<sup>120</sup> can be seen early on in Swedish ethics codes<sup>121</sup>, but is predominantly a manifestation of typical modern thoughts and norms.

Within anatomy and surgery, important achievements had been made. The Dutch physician Andreas Vesalius’ book on the human body “*De humani corporis fabrica*” was presented as early as the 16<sup>th</sup> century and disproved all the medieval practitioners’ conceptions of the structure of the inner organs, which, before this, in large part had relied on dissection of animals.<sup>122</sup>

A couple of decades into the 19<sup>th</sup> century, botanists found that plants were built up of cells. This cell theory was then transferred to the animal kingdom and the understanding of the cell’s importance as a carrier of the organisms’ manifestations of life had great importance for medicinal science. In 1858, the German physician Rudolf Virchow published his pioneering work on cells’ malign cancerous changes. Through this the existing conception of human health being dependent on the four humours was replaced by the theory of cellular pathology.<sup>123</sup>

Research improved in laboratories and with more delicate technique and improved aids, medicine became a true science. From the mid 19<sup>th</sup> century until our day, great progress has been made. Louis Pasteur and Robert Koch made key contributions in bacteriology. Joseph Lister fought wound infections, making surgery possible. Wilhelm Röntgen discovers the X-ray in 1895. The endocrine

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<sup>118</sup> [www.homeopathic.org](http://www.homeopathic.org) (August 2005)

<sup>119</sup> Olsson, S. (red.), *Örtmedicin och växtmagi*, supra 23, page 40.

<sup>120</sup> Below, section 3.2.1.4.

<sup>121</sup> Eklöf, M., *Vetenskap, etik och medicinsk pluralism i Perspektiv på komplementär Medicin*, red. Eklöf, M., 2004 Studentlitteratur, page 214.

<sup>122</sup> Id., page 41.

<sup>123</sup> Id., page 42.

system was researched and insulin manufactured for the first time in 1922.<sup>124</sup> The understanding of the need for vitamins cured many deficiency diseases. Today, many of the diseases that killed millions are virtually wiped out.

With modernism came not only a revolution in scientific knowledge, but also the welfare states' vision of actively creating a better society. Realism was more important than idealism and there was less consideration for events of the past. There was hostility towards religion, and secularisation took place due to this scientific paradigm. Religion was replaced by science, superstition by medication and priests by medical practitioners. Regulatory actions in the form of creating laws were taken to control many aspects of everyday life, and certainly concerning the practice of medicine, the Caregivers and their remedies.

#### **2.2.1.4. Creating order out of chaos**

Modernism was fundamentally about order and rationalization, creating order out of chaos. The assumption was that the more ordered a society was, the better it would function and because of this, modernism meant the pursuit of ever-increasing levels of order. Society was constantly on guard against anything and everything labelled as “disorder,” which might disrupt order. Thus modern societies relied on continually establishing a binary opposition between “order” and “disorder”, to assert the superiority of “order.” But to do this, they had to have things that represented “disorder” and in western culture, this disorder became “the other” - defined in relation to other binary oppositions. Thus anything non-scientific, such as Complementary medicine, became part of “disorder”, and had to be eliminated from the ordered, rational modern society.<sup>125</sup>

Though modernism is a 20<sup>th</sup> century phenomenon, it can be said to have its start at the end of the First World War, that is to say around 1918. After the first World War, there was a need for new role-models within art, literature, music, philosophy, economy, science and within medicine as well.

Secularisation took place in the law, but also in medicine. There was to be no superstition or religion in the healing of patients, but rather science and experience were the only recognized values. It was in connection to scientific progress and parallel to the development of medicine as a scientific subject that licensed doctors were given increasing power, status and authority.<sup>126</sup> The development of a more professional approach in medicinal practice took place, finally resulting in the monopoly of Licensed practitioners for certain types of treatments. During modernism, it is fair to say that the professional actors' position in society was decisively strengthened.

#### **2.2.2. Modernism affects the Caregivers**

An exceptional number of things happened during the modern period concerning the practice of medicine in Sweden. The number of doctors per capita in Sweden

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<sup>124</sup>Porter, R., *The greatest benefit to mankind*, page 11.

<sup>125</sup> This idea is based on an essay by Dr. Mary Klages, Associate Professor, English Department, University of Colorado, found on <http://www.colorado.edu/English/ENGL2012Klages/pomo.html> (August 2005).

<sup>126</sup> Tegern, G., *Medborgarna och den medicinska mångfalden*, in *Perspektiv på komplementär Medicin*, red. Eklöf, M., Studentlitteratur, Lund 2004, page 83.

just before modern times was very low compared to other European countries – there were six times as many doctors in England and three times as many in Germany as there were Sweden in 1850. The number of Licensed practitioners increased dramatically in the next half century, as can be seen below.

	<i>Doctors</i>		<i>Pharmacists</i>	
	<b>1850</b>	<b>1900</b>	<b>1850</b>	<b>1900</b>
Sweden	7 522	3 845	6 948	4 249
England	1 176	1 433	1 277	1 137
Germany	2 665	2 059	10 928	10 367

Number of inhabitants per doctor/pharmacist in Sweden, England and Germany in 1850 and 1900.<sup>127</sup>

The licensed doctors captured a privileged position during this time, unique in comparison to other era's and cultures' medicinal professionals.<sup>128</sup> During Swedish modernism, the profession of medicine is more or less monopolized by them, and non-licensed medical practitioners are forced out of the medical market, not so much by legislation, but by the influencing of public opinion. Medical practitioners had to organize themselves internally, because in their view, politicians and legislators needed to be convinced of the dangers of letting “quacks” continue to work, and the public needed to be warned and mobilized to act against anyone not licensed.

### **2.2.2.1. Influencing Public Opinion**

The public was reached, amongst other things, through popular medicine magazines meant to educate and inform. An example of this type of magazine was *Hygienisk Revy* which was to be an informative medicinal journal and a counterbalance to the alternative medicinal humbug.<sup>129</sup> It was published from 1912 by Torsten Thunberg who was a very strong opponent of quackery. The articles were dominated by the fight against “false” medicine and the authorities' lack of action against the practitioners of such medicine.

It is clear that Licensed practitioners mobilized against quackery in the 1910s, Articles surrounding this theme are predominant in both *Hygienisk Revy* and the Swedish Medical Review around this time<sup>130</sup>. Motions regarding stricter legislation on these matters were put forth in Sweden's medical associations and there was an intense lobbying of politicians. Members of parliament were given subscriptions to *Hygienisk Revy*, often paid by doctors themselves<sup>131</sup>.

### **2.2.2.2. The Quackery debate in Parliament**

The quackery debate in Parliament was heated around the turn of the century. The earliest attempts to bring the question of unlicensed medical practice to the agenda of the parliament were met with resistance. In 1895 a motion was laid

<sup>127</sup> Nelson, M.C., *En historia om vård förr*, supra 52, page 38.

<sup>128</sup> Id., page 83.

<sup>129</sup> Palmblad, E., *Sanningens gränser; Kvacksalveriet, läkarna och samhället, Sverige 1890 – 1990*, Carlssons bokförlag, Stockholm 1997, page 70.

<sup>130</sup> Läkartidningen 1910 nr 7, page 1-14, according to Eklöf, M., *Kvacksalveriet - hett debattämne under hela seklet* in Läkartidningen nr 1-2, 2004, Volym 101, page 119.

<sup>131</sup> Palmblad, E., *Sanningens gränser*, supra 129, page 70.

forward in the first chamber<sup>132</sup>, but it was rejected because it was too much in favour of the Licensed practitioners. The debate centred not only on unlicensed practitioners, but also on the relationship between Licensed practitioners; to organize and clarify the relationships of doctors, nurses, physiotherapists, dental technicians.

In 1896, the question was brought up in the second chamber, where certain members of parliament were opposed to what they assumed to be the Licensed practitioners' attempt to monopolize the art of medicine.<sup>133</sup> This was a threat to the laity and all the good they were doing in regions with few medical practitioners. One had to take into consideration public opinion and not overestimate their faith in Licensed practitioners or underestimate their faith in unlicensed practitioners. Again, the proposal was rejected.

A third motion was laid in 1907<sup>134</sup>, but yet again no legislation was passed due to the fact that it could not be decided how to regulate quackery without bringing harm to valuable unlicensed practitioners. It was decided to examine the question of de-licensing Licensed practitioners, and it is through this examination that the question of quackery was ultimately brought up in the political arena.

On a political level, there was much hesitation regarding special legislation within an area – medicine – favouring one group of professionals – the medical practitioners. It was thought that if this was done for one group of professionals, others would be lining up to get the same advantages and benefits.<sup>135</sup>

*Allmänna Svenska Läkaresällskapet* (Swedish Public Medical Association, later the Swedish Medical Association) asked for drastic measures to be taken regarding quackery. “Something must be done.”<sup>136</sup> Quackery had now become a social problem of such large dimensions that society had to take action.

### 2.2.2.3. The new laws

The “Quackery law” was passed in 1915<sup>137</sup>, and it was the first law to regulate the profession since 1688.<sup>138</sup> It was a result of the demand of the medicinal board and the Licensed practitioners. According to the law, anyone could practice medicine, with precise exceptions: venereal disease, TBC, cancer and contagious diseases were not to be treated professionally by non licensed practitioners. The same was said for hypnosis and anaesthetics<sup>139</sup>. Contraventions were punishable by fines or prison for up to one year.<sup>140</sup>

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<sup>132</sup> Riksdagens protokoll vid lagtima riksmötet år 1895. Första kammaren. Andra bandet. N:is 15-25 (Stockholm 1895).

<sup>133</sup> Riksdagens protokoll vid lagtima riksmötet år 1896. Första kammaren. Första bandet. N:is 1-13 (Stockholm 1896).

<sup>134</sup> Bihang till riksdagens protokoll vid lagtima riksdagen i Stockholm år 1907. Första samlingen. Andra afdelningen. Andra bandet (A.) Motioner, väckta inom Andra kammaren, n:is 1-162 (Stockholm 1907).

<sup>135</sup> Palmblad, E., *Sanningens gränser*, supra 129, page 31.

<sup>136</sup> Proposition Nr 85 (Stockholm 1915), page 8. Bihang till riksdagens protokoll 1915. 1 samlingen. 74 häftet.

<sup>137</sup> Lag (SFS 1915:362) om behörighet att utöva läkarkonsten; given Stockholms slott den 21 september 1915.

<sup>138</sup> Kungl. Maj:ts Medicinalförfordningar av den 30 oktober 1688.

<sup>139</sup> Lag om behörighet att utöva läkarkonsten, supra 137, 6§, 2 mom.

<sup>140</sup> Id. 6§, 2 mom, 2st

The passing of the new law in 1915 did not calm the mobilization of the Licensed practitioners. It was thought that the new law was too vague, and needed complementary amendments as soon as possible. It was seen by the Swedish Medical Association as a half measure which actually protected the unlicensed practice of medicine. Some even argued that the new legislation was more favourable for quacks than the old medicinal ordinances had been, since the absolute monopoly on health care was now gone.<sup>141</sup>

A reaction to the Licensed professionals' campaigns against Complementary medicines and unlicensed practitioners was the creation of an organisation defending the interests of Complementary medicines, *Förbundet för folkhälsans vänner*<sup>142</sup>. Created in 1924, nine years after the new legislation came into force; it campaigned for freedom of choice in the method with which to be treated. It opposed the idea that every non-academically educated medical practitioner was to be seen as a quack. The association argued that a monopoly for any occupational group was a risk, since this might produce a lust for profits and overconfidence in ones own capacity.<sup>143</sup>

The Law of 1915 was replaced in 1960 by a Law Prohibiting Certain Activity in Health Care<sup>144</sup>, also known as the Quackery Law. In this the prohibitions became more extensive than in the Law of 1915. Society, it was thought, should take up a more pronounced negative attitude towards what was then called quackery.<sup>145</sup> If quackery had been tolerated because of a lack of doctors or difficulties in reaching a doctor, these reasons were found to be of less importance now. The law reserved the treatment of a number of diseases and disorder to licensed doctors, and stipulated severe sanctions for those who broke the quackery law. There was a regulation against itinerant activity and treatment by foreigners. This prohibition was abolished by an amendment in 1993.<sup>146</sup>

Both these laws - the law of 1915 and the law of 1960 - are expressions of a critical attitude towards traditional methods of treatment, which is typical of modern ideas and ideals. The demand of professionalisation of Caregivers, scientific methods of treatment and the wish to create order in an area filled with disorder – that is to say the activity of the “quacks”.

### 2.2.3. Modernism and Medicinal Products

With modernism came new Medicinal products, some wanted and accepted, many not. Apart from the folk medical practitioners, new actors entered the market and gave the Complementary medicine sector a much larger spread than before.<sup>147</sup> The licensed medical practitioners' contempt for unorthodox medicine at the turn of the century probably increased because of the amount of medications and methods that flooded the market around this time.

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<sup>141</sup> Almer, *Riksdagsdebatten om kvacksalverilagen*, in *Läkartidningen* 1915 Nr 12 page 833-860.

<sup>142</sup> Palmblad, E., *Sanningens gränser*, supra 129, page 49.

<sup>143</sup> Id., page 50.

<sup>144</sup> Lagen (1960:409) om förbud i vissa fall mot verksamhet på hälso- och sjukvårdens område.

<sup>145</sup> SOU 2004:123, supra 2, page 55.

<sup>146</sup> SOU 2004:123, supra 2, page 58.

<sup>147</sup> Id., page 60.

### 2.2.3.1. Universal medications, patent medicines and Elixirs

It was the golden age of patent medicine. Patent medicines were Medicinal products that were given special authorizations to be used on the basis that they were allegedly patented abroad.<sup>148</sup>

One plausible reason for this was the lack of confidence that scholarly medicine was suffering from during the period in question. Medical practitioners had very little power over the infectious diseases that devastated the population. The market for products offered as an alternative to Conventional medicines expanded, and especially attractive were the elixirs and “universal” medications, which claimed to cure almost every disease known to mankind including preparations against alcoholism and drug abuse. As it turned out, many of these preparations contained the drugs against which they were said to act.<sup>149</sup>

The temptation to believe in these miracle cures is understandable in the light of the wide panorama of diseases over which Conventional medicine and Licensed practitioners were powerless. The trade in this type of patent medicine is perhaps what truly caused a mobilisation against quackery, a battle which now intensified. A demand for legislation concerning the trade of medicine was included in this battle.<sup>150</sup>

### 2.2.3.2. The Pharmacy monopoly

Ever since the early medicinal decrees, there had existed tensions between pharmacists and representatives of free trade, such as spice dealers,<sup>151</sup> concerning the sale of medical drugs. The Collegium Medicum, the Sundhetskollegium and later the Medicinalstyrelsen (The Medicinal Board) had all tried repeatedly to cope with the illegal sales of drugs. Various decrees had regulations on what was reserved for pharmacists to sell. According to the Trade Regulations of 1846<sup>152</sup>, the sale of medical drugs was reserved for pharmacies. The trouble was that there was no definition of medical drugs.<sup>153</sup>

Modern advertisements made it possible for anyone to promote their products. Patent medication had become a huge industry. The opinion that the sale of drugs should be a state monopoly was represented by Torsten Tunberg, a physiologist at the University of Lund.<sup>154</sup> His opinion was that private enterprise meant not only a decrease in quality but an excessive overall use of drugs. The fight had to be not only against this entrepreneurial activity but also against the individuals' tendency towards self-care.

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<sup>148</sup> Ling, S., *Kärringmedicin och vetenskap*, supra 89, page 59.

<sup>149</sup> Id., page 59.

<sup>150</sup> An interesting technical product around this time was the electrical belt, which was said to cure everything from deafness to paralysis. Electricity was in its childhood around the turn of the century and seen as a miracle cure, a powerful healer. Nelson, M.C., *En historia om vård förr*, supra 52, page 43.

<sup>151</sup> supra 68.

<sup>152</sup> 1846 års handelsordning.

<sup>153</sup> Kock, W. (red.), *Medicinalväsendet i Sverige*, Utgiven med anledning av Kungl. Medicinalstyrelsens 300års jubileum (Stockholm 1963).

<sup>154</sup> Id., page 59.

Tensions continued throughout the years around 1900, and pharmacists demanded measures be taken effectively to protect their trade. A proposal was made in 1909, which caused massive protests, and a new statute was enacted in 1913.<sup>155</sup>

The new medicinal drug ordinance of 1913<sup>156</sup> gave pharmacies alone the right to sell medicinal drugs. This state monopoly has remained until contemporary times.

## **2.3. Post-modernism affects health care thinking**

### **2.3.1. Defining post-modernism**

If modernism was the anti-thesis to pre-modernism, then the post-modern time period can be seen as the synthesis of pre-modernism and modernism.<sup>157</sup> The post-modern period can be seen as a reaction to modernism. It represents a transition from a homogenous, monolithic culture to a heterogeneous, multicultural and pluralistic one.<sup>158</sup> Post modernism is marked by the absence of a single dominant style or mode of thought.<sup>159</sup> It can be discussed whether “post”-modernism is the most suitable denomination, since this may imply a rupture with modernism, rather than a successive change of it. Does the term post-modernism imply a decisive break with the past – or an extension and development of modernist programs?<sup>160</sup> In certain subject areas, the term late-modernism may be more appropriate, but in the discussion of quackery, the change is significant enough, and abrupt enough to allow the use of the term post-modernism.

The point at which post-modernism should be considered to begin is not easily decided, and as we are in the middle of it, we have no historical distance to the period. It is therefore difficult to define what exactly the post-modernistic era entails, yet certain tendencies and trends can be seen. It can be seen as a reaction to modernism. It is the late 20th century’s polarising power. The time period brings into light a number of new key-words, including internationalism, individualism, pluralism, commercialisation, and privatization.<sup>161</sup> All of these are terms which are relevant when looking at the development on the medicinal market during the late 20<sup>th</sup> century until now. The impact these tendencies have had on the professional actors’ situation - whether licensed or not - and on the consumers’ choice of method of treatment, and choice of products, is distinct.

This section will not deal with the specific regulations in a legal manner, but rather as historical phenomena. The legal discussion will be carried out in the next chapter.

### **2.3.2. The Caregivers**

With regard to the Caregivers, many changes have been made that are typically post-modern. If the modernist period strengthened the Licensed practitioners’

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<sup>155</sup> Palmblad, E., *Sanningens gränser*, supra 129, page 59.

<sup>156</sup> Kungl. Maj:ts Nådiga apoteksvarustadga, (SFS 1913:308), 14 november 1913.

<sup>157</sup> Modéer, K.Å., *Det nära förflutna*, supra 3, page 179.

<sup>158</sup> Modéer, K.Å., *Det nära förflutna*, supra 3, page 189.

<sup>159</sup> Morris, D., *Illness and Culture in the Postmodern Age*, University of California Press Ltd., London 1998, page 136.

<sup>160</sup> K.Å., *Det nära förflutna*, supra 3, page 24.

<sup>161</sup> Id., Page 189.

position, post-modernism has succeeded in strengthening the patients' position. This does not necessarily mean that the Licensed practitioners' power has decreased, just that there has been a shift in values.

### 2.3.2.1. The Committees

In 1984, an Alternative Medicine Committee (AMK) was set up by the Swedish state in order to analyse the need for legislative change and the public's attitude in general towards alternative therapies and therapists. This exposition resulted in four positive Government Official Reports (SOU)<sup>162</sup>. These reports never resulted in legislative changes, but they show a tendency towards a more positive view of Complementary medicines. This can be seen as an acceptance of pluralism – of many different professional actors on the market. The propositions were an attempt to ocularise all the existing Caregivers, and evidence of the acceptance of heterogeneity within the medical profession. In the post-modern era, the *melting-pot metaphor* of modernism - that is to say the attempt to incorporate all things into one homogenous compilation - is replaced by the *salad bowl metaphor*.<sup>163</sup> This metaphor aims to capture the ideal of heterogeneity - of showing off the different parts of the salad, not creating a single, plain stew.

The same year, another committee - The Committee on Alternative Medicine (KAM) - was founded. KAM is a professional association of societies and schools in the complementary and alternative medicine sector.<sup>164</sup> The association was founded on the basis of the AMK report, and the societies which form KAM decided to produce an accreditation of their own: the final structure of this was established in 1993.

When, in 1994, Sweden voted to join the European Union, this was an indication of the idea that post-modernism includes an internationalist trend. Swedish membership of the Union gives insight into other health care systems, which are often much more accepting of Complementary remedies, and where competition between Licensed professionals and unlicensed professionals is encouraged. There is a liberal tendency in that choices are more plentiful for the patients. Health is an increasingly coveted product area and thereby a profitable arena for many actors. The treatment of illnesses, or perhaps more correctly, the improvement of health, is becoming commercialised and privatized.

### 2.3.2.2. De-professionalisation

There is discussion of the tendencies towards de-professionalisation and proletarianisation in the medical guild in post-modern times. De-professionalisation means that the power and influence of the licensed care givers in the healthcare politics of the western world, has decreased, if not vanished completely.<sup>165</sup> It is now an international, if not global affair, and is often regulated by way of international

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<sup>162</sup> 1. SOU 1989:60, supra 12, 2. SOU 1989:61, *Hälsohem; rapport från en expertgrupp inom alternativmedicinkommittén*, Stockholm 1989, 3. SOU 1989:62, *Alternativa terapier i Sverige, en kartläggning av alternativmedicinkommittén*, Stockholm 1989, and 4. SOU 1989:63, *Värdering av alternativmedicinska teknologier*, Stockholm 1989.

<sup>163</sup> The expression is taken from a lecture with Kjell Åke Modéer at the Faculty of Law at Lund University in November 2004.

<sup>164</sup> [www.kam.se](http://www.kam.se) (August 2005).

<sup>165</sup> Tegern, G., *Medborgarna och den medicinska mångfalden*, supra 126, page 90.



agreements.<sup>166</sup> An increasing number of actors on the medical market has certainly had an impact on the tendencies towards de-professionalisation.

According to the proletarianisation theory, Caregivers - including those that are licensed – have been subordinated by a ruling class of capitalists and business executives.<sup>167</sup> This can be seen as an indication of the commercialisation and privatization, which are all a part of post-modern times.

Legal changes in Sweden, as well as other western countries, have given patients a stronger position in the health care context. This is interpreted by many as a diminution of doctoral power and influence, a de-professionalisation.<sup>168</sup>

### 2.3.3. The Products

#### 2.3.3.1. A holistic view of health

Post-modernism in medicine is characterised amongst other things by an interest in holistic health movements.<sup>169</sup> The approach to health has become more inclusive, and now does not only include avoiding illness, but also maximizing well-being. Products and methods of treatment, which are thought to improve our comfort are as important as those thought to heal our diseases and discomforts.

Complementary therapies include both pharmacological (such as Natural remedies) and non-pharmacological treatments (such as manual treatments and Acupuncture).<sup>170</sup> There is a new spirituality which comes hand in hand with post-modernism, a nostalgic idea that things were better before, and one can see a re-traditionalisation in the return to traditional products and methods of healing<sup>171</sup>. It is acceptable once again to be spiritual and there is a de-secularisation taking place within the therapies available and tolerated in our post-modern society.

These changes in value are clear, as is a focus on our bodies in our choices as consumers of medicinal remedies. There is pluralism, tolerance and a wish for self-realization.<sup>172</sup>

The pluralism on the market can be seen clearly in the fact that there are more than 200 different complementary therapy forms being used in Sweden today, differing greatly in the theories and philosophies on which they are founded.<sup>173</sup> In addition, an indicator might be the some 296 Natural remedies registered with the Swedish MPA, presently available on the market.<sup>174</sup>

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<sup>166</sup> WHO Policy Perspectives on Medicines, No 2 May 2002, *Traditional Medicine – Growing Needs and Potential*, [http://www.who.int/medicines/library/trm/trm\\_polpers\\_eng.pdf](http://www.who.int/medicines/library/trm/trm_polpers_eng.pdf), (August 2005).

<sup>167</sup> Tegern, G., *Medborgarna och den medicinska mångfalden*, supra 126, page 89.

<sup>168</sup> Id., page 90

<sup>169</sup> Id., page 89.

<sup>170</sup> Falkenberg, T., and Hök, J., *Komplementärmedicin och internationell hälsosystemutveckling*, in *Perspektiv på komplementär Medicin*, red. Eklöf, M., Studentlitteratur, Lund 2004, page 49.

<sup>171</sup> Richt, B., *Komplementärmedicin – varför nu?* in *Perspektiv på komplementär Medicin*, red. Eklöf, M., Studentlitteratur, Lund 2004, page 68.

<sup>172</sup> Id., page 67.

<sup>173</sup> SOU 2004:123, supra 2, page 34.

<sup>174</sup> Färnlöf, Å. & Tunón, H., *Naturläkemedel 2000*, below note 296, page 12 <http://www.mpa.se/>

### 2.3.3.2. The Grand Narratives

In a study carried out in Sweden in 1996 called "Beliefs and Values in Sweden of the 90's"<sup>175</sup> the attempt was made to find Swedish peoples views on what was worth striving for. The study showed a loss of our faith in the *Grand Narratives* in our post-modern society.

A Grand Narrative is a narrative that explains (or perhaps contains) all others. For example, there are various narratives all over the world that explain the creation of the universe and everything in it; if a particular story is claimed to be the ultimate one that explains everything properly or accurately, it could be characterised as a Grand Narrative<sup>176</sup>. Postmodernism is sceptical towards the idea of finding one story that explains the world. Postmodernism, in rejecting Grand narratives, favours "mini-narratives," stories that explain small practices, local events, rather than large-scale universal or global concepts. Postmodernism then is the critique of Grand Narratives, the awareness that such narratives serve to mask the contradictions and instabilities that are inherent in any social organization or practice.<sup>177</sup>

The Grand Narrative that the Swedish society should be built on Christian faith or that society should be built on a scientific basis was ranked lowest in the study, whereas good health was ranked as the most important value.<sup>178</sup> One interpretation could be that people believed "scientific" Conventional medicine was not the best remedy for providing good health. This could be seen as a rejection of the Grand Narrative of science and an explanation as to why Complementary medicine's popularity is increasing, perhaps.

In our contemporary society, with regards to medicine, the post-modern desire effectively to return to the pre-modern era tends to get associated with the use of Complementary therapies rather than Conventional medicines and the return to a more comprehensive view of health.

## 2.4. Historical Summary

Before 1688 the competency of Caregivers in Sweden was completely unregulated. After 1688 the opposite was true and licensed doctors in Sweden were given a monopoly on the treatment of diseases.<sup>179</sup> The monopoly was, however, not in fact real, since there did not exist enough Licensed practitioners to fulfil the public's need. In addition, the differences in treatment available from the two groups were miniscule, making the regulation rather unnecessary.

Alongside scientific progress, and due to the Licensed practitioners own demands, a trend towards professionalisation of the medical profession can be seen. There was much discussion on how to legislate on the matter, but finally, the Government's proposition to the Riksdag (the Parliament) did not include a complete penalization of professional quackery.

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<sup>175</sup> Kallenberg, K., Bråkenhielm, C.R., and Larsson G., *Tro och värderingar i 90-talets Sverige; Om samspelet mellan livsåskådning, moral och hälsa*, Libris, Örebro 1996.

<sup>176</sup> <http://www.colorado.edu/English/ENGL2012Klages/pomo.html>, August 2005.

<sup>177</sup> Id.

<sup>178</sup> Kallenberg, K., et al., *Tro och värderingar i 90-talets Sverige*, supra 175.

<sup>179</sup> Kungl. Maj:ts Medicinalförordningar av den 30 oktober 1688.

Instead, the law which came into force on January 1<sup>st</sup> 1916 only imposed restrictions on the “quacks”, and thus legalized their practice, much to the doctoral guilds’ dismay. This law, however, was still a reflection of modern ideas, since it was an attempt to restrict unlicensed practitioners actions in order to more specifically professionalize doctors. In 1960, the law was replaced by two new laws, one of which regulated the competency of licensed doctors, and the other was the *Quackery law*. Not until this period had the doctoral title been protected – this protection being yet another reflection of modern ideas in that it draws an even clearer line between the accepted and the tolerated.

In 1975, the first articles on “Alternative medicines” – as opposed to “quackery” – were published in the Swedish Medical Review, showing that even the group of professionals historically most inclined to be negative, were being forced to come to terms with the idea that they no longer had a monopoly on the successful treatment of diseases. When the Committee on Alternative Medicine was installed in 1984, the post-modern tendencies were clear. Diversity is now accepted and since the proposition of 1989, Complementary medicine has evolved and demanded recognition. The medicinal market is a heterogeneous one, and a re-traditionalisation has occurred. We find ourselves in the pre-modern acceptance of traditional healing methods, and a de-professionalisation of the doctoral guild can be seen.

### 3. The contemporary situation

Having now an understanding of the historical events leading up to the present, it is of interest to see how these events have affected the Swedish legal system. Being a member of the European Union, the Swedish law is now to a large extent determined by European legislation.

In 1958, when the Treaty of Rome, also known as the EC Treaty (hereinafter “the Treaty”)<sup>180</sup>, was signed, Health Care issues were not a part of the European agenda. During the initial years, the Community rather relied on general trade provisions in the Treaty to harmonize certain health related issues. The adoption of Council Directive 65/65/EEC<sup>181</sup>, securing trade in medicinal products is a good example of how health aspects could still be important. Health only became a fully integrated part of the European development with the adoption of Article 129 of the Treaty of Maastricht<sup>182</sup> in 1992. For the first time it was established that “the community shall contribute towards ensuring a high level of human health protection by encouraging co-operation between the Member States(...)”.

Sweden only became bound by the health development through the EES-Agreement<sup>183</sup> in 1993. With the Swedish membership to the European Union, the EU legislation (the *Acquis Communautaire*) became binding also to Sweden. In accordance with fundamental Community principles, Community law has supremacy over national provisions. In the same manner, interpretations made by the European Court of Justice on EU legislation is binding to Swedish legislators.

It is therefore a natural starting point to look at the European legal situation.

#### 3.1. The European legal situation

This section will clarify how European legislation and case-law deal with Paramedical practitioners and their activities in relation to Licensed practitioners. Furthermore, the handling of complementary Medicinal products in relation to Conventional medicine will be judged from an EU-law perspective.

It is therefore necessary to examine the rules applicable for licensed medical practitioners and Conventional medicine so as to investigate if and how they restrict the Complementary medicine activities. Legislation and case-law is limited with regard to Paramedical practitioners and Complementary medicines, but through analogy and *e contrario* conclusions of the rules applicable for the Conventional medicine and Licensed practitioners, we can understand their relation to Complementary medicines.

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<sup>180</sup> Consolidated version of the Treaty establishing the European Community, OJ 2002 C 325.

<sup>181</sup> Directive 65/65/EEC of the Council of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ L 022, 09/02/1965 P. 0369 - 0373

<sup>182</sup> The Maastricht Treaty, Provisions amending the Treaty establishing the European Economic Community with a view to establishing the European Community, OJ C 224., 31/08/1992 P. 078

<sup>183</sup> 94/1/EC, ECSC: Decision of the Council and the Commission of 13 December 1993 on the conclusion of the Agreement on the European Economic Area between the European Communities, their Member States and the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway, the Kingdom of Sweden and the Swiss Confederation, OJ L 001 , 03/01/1994 P. 0001

The Treaty provides that the activities of the Community shall include a contribution to the attainment of a high level of health protection.<sup>184</sup> On the grounds of, amongst other things, the protection of health and life of humans, prohibitions or restrictions on imports and exports may still be made.<sup>185</sup>

In these fields the Community has competence to enact legislation. Over the years, much legislation has been issued with respect to products circulating on the European market, whereas the regulation of the health care policy and the Caregivers has tended to remain a national prerogative.

Relevant legislation and case-law is described below, and will be discussed in the following analytic section.

### **3.1.1. The Caregivers**

The European Council encourages the Member States to develop their health care systems so that Conventional medicine and Complementary medicine can exist side by side and complement each other.<sup>186</sup> Still, the main responsibility in the field of public health lies with the Member States<sup>187</sup>, and the licensing of medical practitioners is regarded as a national matter. Being an internal affair, the subject is therefore largely not regulated by Community law. There are certain guidelines, but Member States are free, in the absence of harmonisation, to legislate as they wish.

#### **3.1.1.1. Mutual recognition of diplomas**

Mutual recognition of competency is required in order to fulfil the demand for a free market for services provided for in the Treaty: all discriminatory treatment based on nationality with regard to establishment and provision of services is prohibited.<sup>188</sup> All Member States are committed to ensuring that national education fulfils the requirements which are the prerequisites for a mutual recognition.

Directive 89/48/EEC<sup>189</sup> contains a general principle that a person allowed to practice a certain profession in his home country according to that country's rules, should also be allowed to practice a corresponding profession in another Member State. If the applicant holds the diploma required in his own Member State for the taking up or pursuit of the profession in question, the host Member State may not, on the grounds of inadequate qualifications, refuse to allow him to pursue that profession on the same conditions as apply to its own nationals. The rules apply to professions requiring higher education as well as other professional activities dependent on the completion of a certain level of education and training.<sup>190</sup>

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<sup>184</sup> The EC Treaty, supra 180, Article 3.

<sup>185</sup> The EC Treaty, supra 180, Article 30.

<sup>186</sup> Falkenberg, T., et al., *Komplementärmedizin*, supra 170, page 58.

<sup>187</sup> Opinion of Advocate General Mischo, Case C-108/96 Grandvision, paragraph 58.

<sup>188</sup> Article 49, the Treaty, supra 180.

<sup>189</sup> Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three years' duration, OJ L 019, 24/01/1989 P. 0016 – 0023, Article 3.

<sup>190</sup> Council Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC OJ L 209, 24/07/1992 P. 0025 – 0045, Preamble (4).

For every regulated occupational group there is a recognition directive and a co-ordination directive. The purpose of the recognition directives is the recognition of competency – of diplomas, certificates and other evidence of formal qualifications. The directives include measures to facilitate the effective exercise of the right of establishment, and of the freedom to provide services in the different Member States. The co-ordination directives aim to co-ordinate the provisions laid down by law, regulation or administrative action in respect of vocational education.<sup>191</sup> The directives are applicable both for the in a self-employed and for those working in an employed capacity.<sup>192</sup> They stipulate the minimum training requirements for the recognition of diplomas, certificates and other national evidence of formal qualification needed for the principle of mutual recognition.<sup>193</sup>

### 3.1.1.2. Medical Doctors

The rules regarding the profession of doctor – a licensed medical practitioner - have been transcribed into a single Directive, namely Directive 93/16/EEC.<sup>194</sup> For licensed medical practitioners, the Directive requires a complete period of medical training comprising at least a six-year course or 5,500 hours of theoretical and practical instruction given in a university or under the supervision of a university<sup>195 196</sup>.

The Community rules do not affect the provisions laid down by law, regulation or administrative action in the Member States, which prohibit companies or firms from practicing medicine or impose on them certain conditions for such practice.<sup>197</sup>

### 3.1.1.3. Discrepancies in demands of education

Difficulties may arise when the Member States have different requirements for education for paramedical services within their territories. This became obvious in *Case C-61/89, “Bouchoucha”*.<sup>198</sup>

Mr Bouchoucha held a diploma in osteopathy issued in Great Britain. He was charged with having illegally practiced medicine in Nice by practicing as an osteopath though not qualified as a doctor, as required by French national law. Question arose whether it was contrary to Article 52 (now 43) of the Treaty on freedom of establishment to prohibit him from practicing osteopathy in France. The Directives applicable to the case<sup>199</sup> related only to the profession of “doctor” and contained no Community definition of what activities were to be regarded as those of a doctor.

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<sup>191</sup> ECJ, C-371/97, *Gozza v Università degli Studi di Padova*, 3 October 2000, [2000] ECR I-07881.

<sup>192</sup> Council Directive 93/16/EEC, of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications. OJ L 165, 07/07/1993 P. 0001-0024, Article 1.

<sup>193</sup> SOU 1996:138, *Ny behörighetslagstiftning på hälso- och sjukvårdens område m.m.*

<sup>194</sup> Dir 93/16/EEC, supra 192.

<sup>195</sup> Dir 93/16/EEC, supra 192, Article 23(2).

<sup>196</sup> The Directive has been implemented in the Swedish Health Care Act, where it is stipulated that those fulfilling the demands of education for a general medical practitioner in the Directive 93/16/EEC are denominated “European doctors”, (*Europaläkare*, according to LYHS, below note 256, 3:8.) and are given competency to act as medical doctors in Sweden.

<sup>197</sup> SOU 1996:138, supra 193.

<sup>198</sup> ECJ, C-61/89, *Bouchoucha*, 3 October 1990, [1990] ECR I-3551.

<sup>199</sup> Dir 75/362/EEC and Dir 75/363/EEC, now replaced by Dir 93/16/EEC

The Court observed that in so far as there is no Community definition of medical acts, the definition of acts restricted to the medical profession is a matter for the Member States. Each Member State is free to regulate the exercise of that activity within its territory provided only that there must be no discrimination between its own nationals and those of other Member States. The court ruled that “in the absence of harmonization at Community level regarding activities which fall solely within the scope of the practice of medicine, Article 52 (now 43) of the Treaty does not preclude a Member State from restricting an activity ancillary to medicine (...) exclusively to persons holding the qualification of doctor of medicine.”<sup>200</sup>

The *Bouchoucha* case specifically answered the question with regards to osteopathy, but it is likely that any activity ancillary to medicine is affected by the outcome of the case. Hypothetically, a licensed homeopath from Germany could not come to Sweden and claim to be allowed to treat cancer – in violation of the Swedish Medical Act’s 4<sup>th</sup> chapter - on the basis that he may do just that in Germany.

Bouchoucha performed a medical service within the scope of Conventional medicine as stipulated in French national law. Paramedical services have also been addressed in relation to tax treatment. According to Article 2(1) of the Sixth Council Directive<sup>201</sup> (hereinafter the Sixth Directive) VAT is chargeable on the supply of goods or services. Art 13A(1) of the Sixth Directive prescribes that Member States shall exempt (b) hospital and medical care and closely related activities, (c) the provision of medical care in the exercise of the medical and paramedical professions and (g) the supply of services of goods closely linked to welfare. *Case C-45/01, “Klinische Psychologie”*<sup>202</sup> concerns the tax-exemption of specific services of a charitable foundation in accordance with the Sixth Directive. The question was whether the services of qualified, licensed psychotherapists, who were not registered as doctors, were qualified as services closely related to hospital and medical care within the meaning of the Sixth Directive.

The Court found that in order to be considered as “medical care”, the care must have as its purpose the diagnosis, treatment, and, as far as possible, cure of diseases or health disorders.<sup>203</sup> The term “medical care” in 13A does not call for a especially narrow interpretation.<sup>204</sup> According to the Court the notion “must be interpreted as covering all provision of medical care (...) including services provided by persons who are not doctors, but who provide paramedical services”<sup>205</sup>.

In *Case C-108/96, “Grandvision”*<sup>206</sup>, national Belgian legislation prohibited opticians from carrying out certain optical examinations and the question arose whether this legislation was compatible with Art 28, 43 and 49 of the EC Treaty.

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<sup>200</sup> Case C-61/89, supra 198, paragraph 16.

<sup>201</sup> Sixth Council Directive 77/388/EEC of 17 May 1977 on the harmonisation of the laws of the Member States relating to turnover taxes – Common system of value added tax: uniform basis of assessment, OJ 1977 L 145, paragraph 1.

<sup>202</sup> ECJ C-45/01, *Klinische Psychologie v Finanzamt Gießen*, 6 November 2003, [2003] ECR I-12911.

<sup>203</sup> Case C-45/01, supra 202, paragraph 48.

<sup>204</sup> Id., paragraph 49.

<sup>205</sup> Id., paragraph 50.

<sup>206</sup> ECJ C-108/96, *Grandvision Belgium v Union professionnelle belge des médecins spécialistes en ophtalmologie et chirurgie oculaire*, 1 February 2001, [2001] ECR I-837.

Under the rules on freedom to provide services, could opticians who are established in one Member State, be prohibited by the national rules of another Member State from carrying out examinations in the latter State?

The Commission stated that in the absence of specific Community rules, each Member State is free to regulate the practice of a profession on its territory. As stated in the *Bouchoucha* judgement (see above), this freedom includes the power to determine which acts may exclusively be carried out by doctors, since there is no Community definition of *medical activities*. However, the Member States may not discriminate between its own nationals and those of other Member States.<sup>207</sup> The Court found that Belgium could reserve certain optical examinations to a category of professionals holding specific qualifications, for reasons relating to the protection of public health.

### 3.1.2. The products

Since medicinal remedies are *products*, these are carefully and specifically regulated so as to align national laws and administrative provisions in order to promote the functioning of the internal market as well as guaranteeing high quality and safe products. Medicinal products are regulated in Directive 2001/83/EC<sup>208</sup> hereinafter referred to as the Community Code.

In order to be qualified as a *Medicinal product* according to the Community Code, a product must include substances “presented as having the ability to treat or prevent diseases”<sup>209</sup> or “which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings”<sup>210</sup>. The directive thus provides two definitions of Medicinal product: one definition “by presentation” and another definition “by function”.<sup>211</sup> A product is a Medicinal product if it comes within one or the other of those two definitions. This then, includes products such as homeopathic and Natural remedies. They are, however, further defined in other directives amending the Community Code.

#### 3.1.2.1. A single Community system

The Community code entered into force in November 2001, however it consolidates legislation dating back to 1965.<sup>212</sup> Its essential aim is to safeguard public health, but this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in Medicinal products within the Community.<sup>213</sup> Hindrances of the functioning of the internal market in the form of disparities between national provisions must be removed.<sup>214</sup> The Directive

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<sup>207</sup> Case C-61/89, *supra* 198, paragraph 23.

<sup>208</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use OJ L 311, 28/11/2001 P. 0067 – 0128.

<sup>209</sup> Dir 2004/27/EC, *supra* 14, Article 1 (2) (subparagraph 1).

<sup>210</sup> Dir 2004/27/EC, *supra* 14, Article 1 (2) (subparagraph 2).

<sup>211</sup> ECJ, Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03, *HLH Warenvertriebs GmbH v Bundesrepublik Deutschland*, 9 June 2005, [2005] ECR n.y.p.

<sup>212</sup> Dir 65/65/EEC had the same basic definition of medicinal product.

<sup>213</sup> Dir 2001/83/EC, *supra* 208, preamble (2) and (3).

<sup>214</sup> *Id.*, preamble (5).



represents an important step towards achieving the objective of the free movement of Medicinal products, though it is understood that further measures will be needed to abolish remaining barriers.<sup>215</sup>

The systems for marketing authorisations involve three procedures: centralised, decentralised (mutual recognition) and national.

Before being placed on the market of a Member State, any Medicinal product must have been given a marketing authorization by the competent authorities of that Member State. The exact procedure for this can be found in Articles 8-12 of the Community Code. Only applicants established in the Community can be granted marketing authorization.<sup>216</sup>

The authorization awarded is valid for five years, though the authorization holder must take into account scientific and technical progress, and must follow generally accepted scientific methods.<sup>217</sup>

The Community code objective, to safeguard public health by means which will not hinder the development of the pharmaceutical industry or trade in Medicinal products within the Community<sup>218</sup>, is implemented mainly in the fourth chapter, concerning the mutual recognition of authorizations. A pharmaceutical company wishing to market a Medicinal product in more than one Member State must use either the centralised procedure or the mutual recognition procedure. The mutual recognition can be achieved by asking another Member State to mutually recognise, within 90 days, the marketing authorisation granted by the Reference Member State.<sup>219</sup> Thus, rapid access to a single market, with the necessary safeguards for the protection of public health, can be obtained using the principle of mutual recognition.

In order to facilitate the mutual recognition of authorizations, a Committee for Proprietary Medicinal Products is set up in Article 27 of the Community code. This Committee is in charge of granting, variation, suspension or withdrawal of marketing authorization. This Committee has its own procedural code, but the main mode of procedure is found in Articles 28-38. However, Homeopathic products are explicitly excluded from this procedure.

In order to manufacture Medicinal products within the Community, a manufacturing authorization from a Member State is needed. This manufacturing authorization is required even if the Medicinal products manufactured are intended for export.<sup>220</sup> The Community Code requires all Medicinal products for human use manufactured or imported into the Community, including Medicinal products intended for export, to be manufactured in accordance with the principles and guidelines of good manufacturing practice.<sup>221</sup>

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<sup>215</sup> Id., preamble (14).

<sup>216</sup> Dir 2001/83/EC, supra 208, Article 8 (2).

<sup>217</sup> Id., Articles 23 and 24.

<sup>218</sup> Id., preamble (2) and (3).

<sup>219</sup> Notice to applicants, Volume 2A, Procedures for marketing authorisation, Chapter 2 Mutual recognition, November 2002, European Commission, The rules governing medicinal products in the European Union, page 1.

<sup>220</sup> Dir 2001/83/EC, supra 208, Article 40.

<sup>221</sup> "Good manufacturing practice" means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use, according to Article 2(6) of Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect

### 3.1.2.2. Natural remedies

Natural remedies are Medicinal products. As long as a substance or combination of substances are presented for treating or preventing disease in human beings, the product is regarded as a Medicinal product unless otherwise specified. However, Directive 2004/24/EC<sup>222</sup>, which came into force in March 2004, amends the Community Code. Herbal medicinal products are now described as “any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbals preparations”<sup>223</sup>

The advent of the pan-European marketing authorisation system has raised a number of questions about Natural remedies and their possible transfer to other European markets.

In order to obtain a marketing authorisation, manufacturers of medicinal herbal remedies are required to demonstrate that their products meet acceptable standards of quality, safety and efficacy. The efficacy requirement, however, is not as strict as for other Medicinal products, the most important factor being that the manufacturers can show that it is not harmful in any way, by use of literature rather than by the normal clinical trials.

*Case C-405/95, “Bioforce”*<sup>224</sup>, which is a customs classification case, demonstrated that the important factor for determining the classification of a Natural remedy is not that it is effective. In the case, the Principal Revenue Office stated that the preparations in question – Echinacea based Medicinal products - could not be classified as medicaments, since “the active substances in Echinacea have not as yet found general recognition”<sup>225</sup>. This view was, however, rejected by the Court. “The description of a product as a medicament in Community legislation or in the national legislation of the Member States, or in any pharmacopoeia is not the deciding factor in so far as its classification (...) is concerned”<sup>226</sup>. Instead it should be considered whether the products have the objective characteristics and properties defined in the Common Custom Tariff, which must be interpreted in the light of medical developments.

A further amendment was made in Directive 2004/24/EC concerning herbal Medicinal products in distinguishing those considered to be *traditional*.<sup>227</sup> The Directive allows for Medicinal products with a long tradition, to be put on the market even if they do not fulfil the requirements of a well-established medicinal use with recognised efficacy and an acceptable level of safety within the meaning of the Community Code. The Directive provides a simplified registration procedure for these products. This procedure should, however, only be used where no

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of medicinal products for human use and investigational medicinal products for human use, OJ L 262, 14/10/2003 P. 0022 – 0026.

<sup>222</sup> Council Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. OJ L136, 30/04/2004 P. 0085 – 0090.

<sup>223</sup> Dir 2004/24/EC, supra 222, Article 1.1.

<sup>224</sup> ECJ, C-405/95, *Bioforce GmbH v Oberfinanzdirektion München*, 15 May 1997. [1997] ECR I-02581.

<sup>225</sup> Case C-405/95, supra 224, paragraph 5.

<sup>226</sup> Id., paragraph 11.

<sup>227</sup> Dir 2004/24/EC, supra 222.

marketing authorisation can be obtained pursuant to the Community Code.<sup>228</sup> Traditional herbal Medicinal products must be shown by bibliographical or expert evidence to have been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community in accordance with Community Code.<sup>229</sup> If this can be shown, along with certain other specified requirements, the product can be registered in a traditional-use registration.

### 3.1.2.3. Homeopathic products

Homeopathic products are prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia.<sup>230</sup>

Until the beginning of the 1990's, homeopathy was officially recognised in certain Member States, while it was not tolerated in others, even though homeopathic drugs were prescribed and used in all Member States. Directive 92/73/EC, replaced now by the Community Code, was the first official recognition of homeopathic drugs in all Member States. It gave rise to the establishment of a special simplified registration procedure for homeopathic drugs in the Community. This registration procedure is available only to products satisfying these conditions:

- administered orally or externally;
- without specific therapeutic indication on the labelling of the Medicinal product; and
- there is a sufficient degree of dilution to guarantee its safety.<sup>231</sup>

The pharmaceutical quality and the batch-to-batch homogeneity of the Homeopathic products are to be demonstrated by the inclusion of certain listed documents in the application for the simplified registration.<sup>232</sup> If the Homeopathic product does not fulfil the criteria in Article 14, they are to be authorized in accordance with the registration procedure of Medicinal products as described in Articles 8, 10 and 11 of the Community Code. Homeopathic products cannot benefit from the traditional medicinal products directive, irrespective of the amount of time they have been on the market.<sup>233</sup>

*Case C-444/03, "Meta Fackler KG"*<sup>234</sup> concerned the registration of a new Medicinal product composed of a new *combination* of known homeopathic substances. The German Federal Health Authority refused the registration since the general awareness of its use as a Homeopathic product had not been proved. The question to be answered was whether only "traditional" Homeopathic products were subject to the special simplified registration procedure and whether a Medicinal product could be seen as "traditional" even if it had not been in actual homeopathic use in that combination.

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<sup>228</sup> Id., preamble (4).

<sup>229</sup> Dir 2001/83/EC, supra 208, Article 16c(1)(c).

<sup>230</sup> Dir 2004/27/EC, supra 14, Article 1, (5).

<sup>231</sup> Dir 2001/83/EC, supra 208, Article 14.

<sup>232</sup> Dir 2001/83/EC, supra 208, Article 15.

<sup>233</sup> Dir 2004/24/EC, supra 222, preamble (4).

<sup>234</sup> ECJ, C-444/03, *Meta Fackler KG v Bundesrepublik Deutschland*, 12 May 2005, [2005] ECR n.y.p.

The Court ruled that as long as the homeopathic “ingredients” fulfil the criteria listed in Article 14 of the Community Code and are prepared from products, substances or combinations called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia, then the special simplified registration procedure should be permitted and a national rule contrary to this cannot be accepted.

The Court developed its position with regard to import/export between Member States of Homeopathic products, in *Case C-212/03, “Commission v France”*<sup>235</sup>.

One of the questions referred to the Court was whether France could require prior authorisation for personal imports of Homeopathic products. The products had been prescribed in France and registered in another Member State in accordance with Community law. The Court found that, where a Homeopathic product is registered in a Member State, it does not, a priori, present any health risk, given that only Homeopathic products with a sufficient degree of dilution to guarantee their safety may be registered, and that, in addition, the rules relating to the manufacture and control of Homeopathic products have been harmonised.<sup>236</sup> In demanding prior authorisation for the importation of Homeopathic products, France was in breach of the prohibition on quantitative restriction on imports and free movement of goods between Member States.<sup>237</sup> The French Government had not shown that a prior authorisation procedure was necessary, on grounds of health protection.<sup>238</sup>

#### **3.1.2.4. Products falling under multiple categories**

Difficulties arise when products fall within the category of Medicinal products in accordance with the Community Code, but also fall into another category, for example food preparations. In the *Bioforce case*<sup>239</sup> the question was if an Echinacea-based product should be classified as a medicament, a food supplement or a spirituous beverage. The court established that a product “does not have to possess any objective qualities making it suitable for therapeutic or prophylactic uses, but that just the overall presentation of the preparation (information on its use, and its packaging, dispensation and marketing), that is to say its subjective purpose, is sufficient for such a classification.”

This position was maintained in *Case C-328/97, “Glob-Sped”*<sup>240</sup>, which concerned the tariff classification of products as medicaments, food preparations or provitamins and vitamins. Glob-Sped wanted to classify vitamin C preparations as medicaments for fiscal reasons, but the German Customs Office claimed that the products were to be classified as food preparations. The Court referred to the *Bioforce case* and found that the subjective qualities were enough for the Court to rule that the vitamin preparations were to be classified as medicaments.

*Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03, “HLH Warenvertriebs GmbH v Bundesrepublik Deutschland”*<sup>241</sup> concerned products

<sup>235</sup> ECJ, C-212/03, *Commission of the European Communities v French Republic*, 26 May 2005, [2005] ECR n.y.p.

<sup>236</sup> Case C-212/03, supra 235, paragraph 20.

<sup>237</sup> EC Treaty, supra 180, Article 28.

<sup>238</sup> Case C-212/03, supra 235, paragraph 28.

<sup>239</sup> Case C-405/95, supra 224.

<sup>240</sup> ECJ, C-328/97, *Glob-Sped AG v Hauptzollamt Lörrach*, 10 December 1998, [1998] ECR I-08357.

<sup>241</sup> *Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03*, supra 211.

falling into a certain classification category in the Member State of importation and into another category in the Member State of exportation.

For the purposes of determining whether a product should be classified as a Medicinal product or as a foodstuff within the meaning of the Community regulations, the competent national authority must decide on a case-by-case basis, taking into account all of the characteristics of the product (...).<sup>242</sup>

The Court found that only the provisions of Community law specific to Medicinal products apply to a product, which satisfies equally well the conditions for classification as a foodstuff and the conditions for classification as a Medicinal product.<sup>243</sup> This ruling has been reduced to law in the new Directive 2004/27/EC, which introduces a new Article 2 into the Community Code, paragraph 2 of which is worded as follows:

In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation, the provisions of this Directive shall apply.

### **3.1.2.5. Free movement requirement**

Member States are not allowed to render difficult the movement of products across borders within the Union. In the above-mentioned case *Commission v France*<sup>244</sup>, the French Republic had applied prior authorisation procedures for personal imports, not effected by personal transports, of certain Medicinal products, including Medicinal products which were authorized in both the country of import and the country of export. The Court found these procedures to be in breach of the obligations under Article 28 of the Treaty.<sup>245</sup> In many other cases, the Court has judged the same to be true. *Case C-221/00, “Commission v Republic of Austria”*<sup>246</sup> deals with Austrian national legislation going beyond EU requirements with regards to labelling of food stuffs. Austria forbade any health related statements on food stuffs even if the information was not liable to mislead the consumer. The principle of proportionality did not justify a system as restrictive of the free movement of goods. Prior authorisation for all health-related information on the labelling of foodstuffs, including those which are manufactured lawfully in other Member States, exceeded the acceptable.<sup>247</sup>

The only allowed restrictions on the import/export of medicinal products are, in accordance with Art 30 of the Treaty, those justified with respect to the need to protect human life. However, Member States should be able to justify any obstacle on a sound technical or scientific basis, by proving that it is absolutely necessary, to demonstrate that a measure giving rise to an obstacle is in proportion to the public interest objective.<sup>248</sup>

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<sup>242</sup> Id., paragraph 30.

<sup>243</sup> Id., paragraph 45.

<sup>244</sup> Case C -212/03, supra 235.

<sup>245</sup> Id.

<sup>246</sup> EJC, C-221/00, *Commission of the European Communities v Republic of Austria*, 23 January 2003, [2003] ECR I-01007.

<sup>247</sup> Case C-221/00, supra 246, paragraph 48.

<sup>248</sup> [www.europa.eu.int](http://www.europa.eu.int), Commission Communication on mutual recognition and the free movement of goods – frequently asked questions (MEMO/03/212), (January 2004).

*Case C-322/01, “Deutscher Apothekerverband”*<sup>249</sup> concerned mail order importation of Medicinal products from one Member State to another and whether national legislation prohibiting such importation was a measure having an effect equivalent to a quantitative restriction for the purposes of Article 28 EC.

The Court found that “a national prohibition on the sale by mail order of medicinal products, the sale of which is restricted to pharmacies in the Member State concerned, (...) is a measure having an effect equivalent to a quantitative restriction for the purposes of Article 28 of the Treaty”.<sup>250</sup>

Also, it was stated that Article 30 of the Treaty may be relied on to justify a national prohibition on the sale by mail order of Medicinal products which may be sold only in pharmacies in the Member State concerned in so far as the prohibition covers Medicinal products *subject to prescription*. However, the Article cannot be relied on to justify an absolute prohibition on the sale by mail order of Medicinal products which are *not* subject to prescription in the Member State concerned.<sup>251</sup>

Sale by mail order of complementary Medicinal products, must then be considered to be acceptable.

The Community Code precludes a national prohibition on advertising the sale by mail order of Medicinal products which may be supplied only in pharmacies in the Member State concerned, (...) in so far as the prohibition covers Medicinal products which are *not subject to prescription*.<sup>252</sup>

### 3.1.3. Summary

**Caregivers** within the Union are allowed to practice medicine in all Member States, provided that they have the required medical training, regardless of whether this is Conventional medicinal activities or Paramedical activities. However, Member States may restrict activities ancillary to medicine exclusively to persons holding the qualification of licensed medical practitioner.

**Products:** Natural remedies and Homeopathic products are both regarded as Medicinal products in accordance with the Community code, since they are “presented as having the ability to treat or prevent diseases”.

*Natural remedies* contain one or more herbal substances as their active ingredients. In order to obtain marketing authorisations, manufacturers of Natural remedies must show that their products meet acceptable standards of quality, safety and efficacy. Medicinal products with a long tradition (at least 30 years, including at least 15 within the community) can be put on the market as traditional herbal medicines.

*Homeopathic products* are also covered by the medicinal legislation, even if special rules apply.

Once given a marketing authorization by the competent authorities of a Member State, this is to be recognized by the other Member States. Natural remedies and

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<sup>249</sup> ECJ, C-322/01, *Deutscher Apothekerverband eV v 0800 DocMorris NV*, 11 December 2003, [2003] ECR I – 07881.

<sup>250</sup> Case C-322/01, *supra* 249, Court ruling.

<sup>251</sup> Case C-322/01, *supra* 249, Court ruling.

<sup>252</sup> Dir 2001/83/EC, *supra* 208, Article 88(1).

Homeopathic products are subject to free circulation in the Community. Member states may not introduce arbitrary rules which prevent this free flow of goods, nor may they introduce rules that provide more burdensome restrictions on Natural remedies and Homeopathic products than required by Community law. Products falling under multiple classification categories may be classified as Medicinal products if they are likely to be perceived as such.

## 3.2. The Swedish legal situation

On the whole, Swedish national legislation must be adapted to European rules, though there is margin for some self-determination. Community law, for example, regulates different professionals. Once the rules on education and vocational training have been harmonised, the actors are free to provide their services throughout the Community. However, national law decides the limits within which such actors may perform their duties as long as the rules are the same for all and not discriminatory against foreign nationals.

### 3.2.1. The Caregivers

As discussed previously, historically Sweden has had a small number of licensed medical practitioners vis-à-vis the population figures. Doctors were few and far between, and turning to alternative therapists has always been – if not encouraged – at least accepted by Swedish law. Politicians have not found any reason to completely forbid these “others” to work, which has ensured that the licensed medical practitioners – much to their dismay – have not achieved a monopoly on health care in Sweden.

The Licensed practitioners have, however, distanced themselves from what they refer to as “quacks”, even though this medicinal practice has been entirely legal. This negative attitude towards Paramedicinal services can be seen in the Swedish Medical Review (Läkartidningen), by and for licensed doctors, where Complementary medicine is many times explicitly referred to as quackery.<sup>253</sup> Around 750 Articles were published in the Review on the subject quackery/Complementary medicine in the period 1904-2003.<sup>254</sup>

The Licensed practitioners’ activity has been defined as scientific and thereby legitimate, making other activity unscientific and illegitimate. This viewpoint will be discussed.

#### 3.2.1.1. The Health Care Acts

Two Acts concern the Caregivers and their rights and duties in Sweden. The Health Care Act<sup>255</sup> (hereinafter HSL) and the Health Care Act regarding the Professional Actors acting within Health Care<sup>256</sup> (hereinafter LYHS).

In common to all groups practicing medicinal care is HSL’s, Health Care Personnel and Paramedicinal practitioners – Caregivers, in general – are obliged to promote good health and good care on equal terms for the entire population.<sup>257</sup>

*Good care is*

- To be of good quality, ensuring the patients feel secure in their care and treatment

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<sup>253</sup> See for example Läkartidningen Volym 95, Nr 3 1998, *Europaparlamentet vill legitimera kvacksalveriet!*

<sup>254</sup> Eklöf, M., *Kvacksalveriet - hett debattämne under hela seklet*, supra 130, page 116.

<sup>255</sup> Hälso- och sjukvårdslag (1982:736).

<sup>256</sup> Lag (1998:531) om Yrkesverksamhet på Hälso- och Sjukvårdens område (“LYHS”).

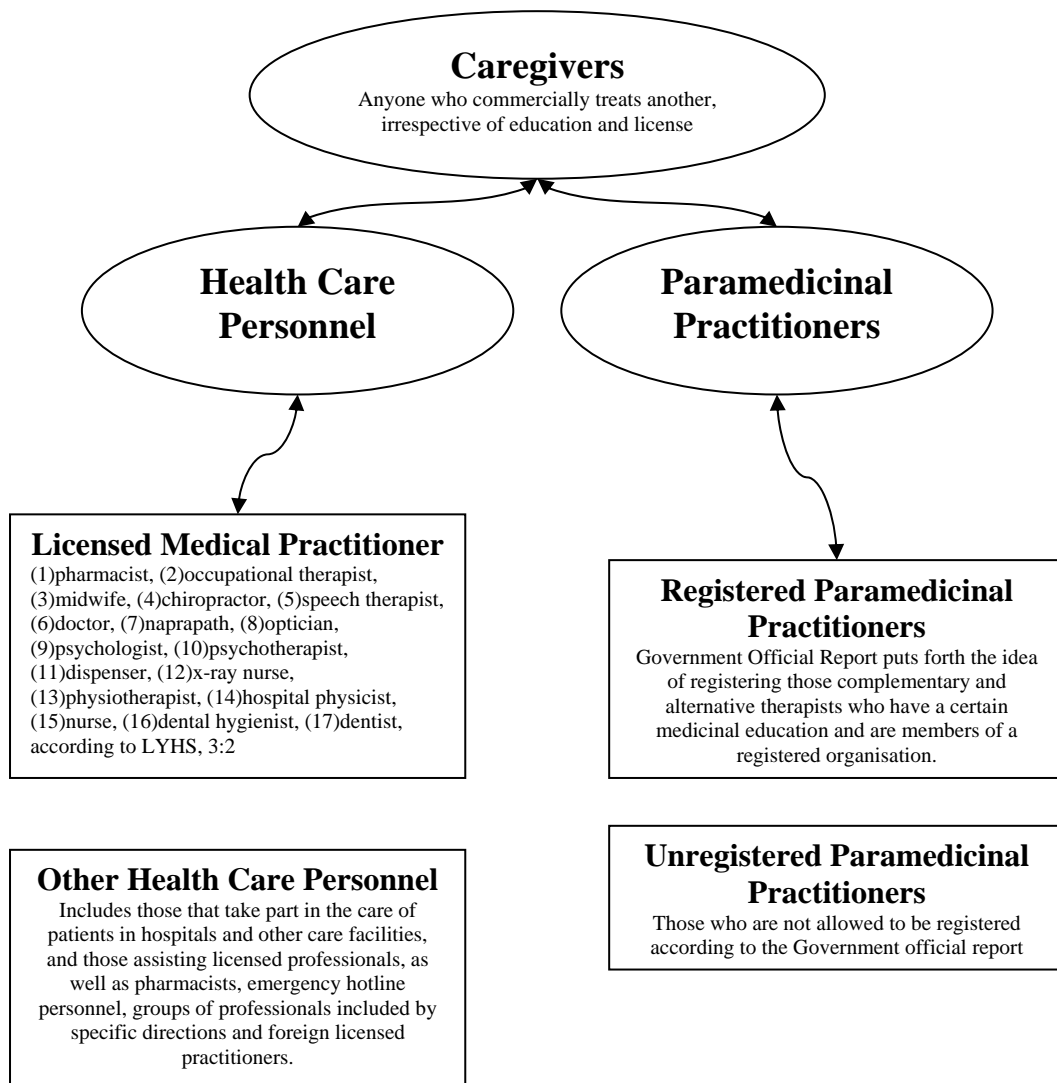
<sup>257</sup> HSL, 2§, supra 255.



- Easily accessible
- To be founded on respect for the patient's self decision and integrity
- To promote good contact between Caregiver and caretaker<sup>258</sup>

These criteria are to be met without distinguishing between the Caregivers as is later done in LYHS. Good care is to be given by anyone taking action to medically prevent, examine and treat disease and injuries.<sup>259</sup>

The following table illustrates the organisation of Health Care professionals in Sweden.



### 3.2.1.2. The Licensed professionals

LYHS defines Health Care Personnel and the scope of their rights and duties. It is stated that Health Care Personnel includes those that are licensed and use one of the protected professional titles listed in the Act's third chapter. There are presently

<sup>258</sup> HSL, 2a§, supra 255.

<sup>259</sup> HSL, 1§, supra 255.

seventeen licensed professions<sup>260</sup> with protected titles<sup>261</sup>. Personnel who take part in the care of patients in hospitals and other care facilities, and those assisting licensed professionals are also considered to be Health Care Personnel as defined by LYHS, as well as pharmacists, emergency hotline personnel, groups of professionals included by specific directives and foreign Licensed practitioners – the so called “European doctors”.<sup>262</sup> It is important to point out that this list is exhaustive, leaving out all and any other form of care or Caregivers from the Act’s advantages for Health Care Personnel, such as their sole right to the actions listed in the fourth chapter of LYHS.

The license has different legal consequences for different professional groups. Doctors, dentists and midwives, for example, benefit from the exclusive right to practice the profession, to the professional title and to the professional term – that is to say the respective professional title in combination with the term “licensed”. Psychologists are given the right to the professional title and the professional term, whilst other licensed professional groups are given protection for the professional term<sup>263</sup>.

The most important significance of the licenses is, however, that it gives society a possibility of reacting - in a noticeable and distinct way - when a Licensed professional seriously neglects his undertakings, by simply revoking it.<sup>264</sup>

### 3.2.1.3. The Paramedicinal practitioners

The other Caregivers – that is, the Paramedicinal practitioners - can be defined a contrario by the same paragraph, as health care providers not falling under any of these categories. They are then further defined as those who commercially examine another’s’ health situation or treats another for illness by measures taken or prescribed with the purpose of preventing, curing or alleviating illness.<sup>265</sup> It is specifically pointed out that the work of Health Care Personnel falling under the scope of the earlier definition is excluded from the limitations stated in the fourth chapter<sup>266</sup>, commonly referred to as the *Quackery Law*. The quackery law was first introduced as such in the Quackery Law of 1961. It has since then undergone many changes, though the general gist of it remains the same.<sup>267</sup> In fact, even today the term “quackery” can be found in the register of the Swedish Civil Law Book, referring to this fourth chapter of the Health Care Act.

In order to ensure the public’s safety, there has been a Government Official Report (SOU) which suggested the introduction of a national register of the Paramedicinal practitioners and a new law to regulate this register: “The law on a national register over persons practicing alternative or Complementary

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<sup>260</sup> (1)pharmacist, (2)occupational therapist, (3)midwife, (4)chiropractor, (5)speech therapist, (6)doctor, (7)naprapath, (8)optician, (9)psychologist, (10)psychotherapist, (11)dispenser, (12)x-ray nurse, (13)physiotherapist, (14)hospital physicist, (15)nurse, (16)dental hygienist, (17)dentist, according to LYHS, 3:2, supra 256.

<sup>261</sup> Three professional titles of these 17 professions are *omitted* from being protected; chiropractor, naprapath, and optician, according to LYHS, 3:5, supra 256.

<sup>262</sup> LYHS, 1:2, supra 256.

<sup>263</sup> SOU 1996:138, supra 193.

<sup>264</sup> SOU 1996:138 supra 193, page 292.

<sup>265</sup> LYHS, 4:1, supra 256.

<sup>266</sup> LYHS, 4:1, supra 256.

<sup>267</sup> SOU 1996:138, supra 193, page 47.

medicine”.<sup>268</sup> The idea is that this register would increase patient safety through ensuring that those registered have a basic medicinal education (corresponding to 20 weeks of full-time studies), that the professional organisations within the alternative- and Complementary medicinal sphere collaborate, and that only members of these professional organisations may register – meaning that they are tied to the objectives and ethical rules stipulated by the organisations.<sup>269</sup> Registration is to be voluntary, and not a prerequisite for being allowed to professionally practice Complementary medicine<sup>270</sup>. If this suggestion goes through, it would divide up the Paramedicinal practitioners into two subcategories: the registered Paramedicinal practitioners and the unregistered Paramedicinal practitioners.

Some specific restrictions apply concerning the two groups of Caregivers respectively. Those providing Paramedicinal services may *not* treat certain groups of patients nor certain conditions. The conditions include illnesses such as cancer, contagious diseases, diabetes, epilepsy, and illnesses occurring in association with pregnancy or birth.

The Paramedicinal practitioners may not use general anaesthetics or local anaesthetics by injection, hypnosis or treatment using radiological methods. They are explicitly prohibited from giving advice or directions without meeting with the patient personally. In addition, unlicensed Caregivers may not try out or supply contact lenses.<sup>271</sup> The amendment related to contact lenses came about in a legislative addition in 1983 and was motivated by concern for patient’s need for medicinal security.<sup>272</sup>

Children under the age of eight may never be examined or treated by the group of Caregivers not defined as Health Care Personnel.<sup>273</sup>

#### **3.2.1.4. Science and Verified Experience**

Though not easily noticeable, Health Care Personnel are also subject to certain restrictions. In addition to their professional secrecy, Licensed practitioners *must* perform their work in accordance with *Science and Verified Experience*. Though this may not at a first glance seem much of a restriction, it is of central importance in understanding the term “quackery”.

Being in accordance with science has been a criterion for legitimate medicinal activity for many centuries. It has been an ideal, a norm and a way of drawing boundaries in medicine and healthcare. The interpretation of the term is negotiable, shifting its meaning in time and space depending on general developments in society and in accordance with foreign influences.

In Sweden, the Sundhetskollegium demanded that all medical practitioners and surgeons after exams should swear an oath before the kollegium. In accordance with the Doctoral Oath of 1829, the doctor to-be swore to use only remedies which

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<sup>268</sup> SOU 2004:123, supra 2, page 13.

<sup>269</sup> SOU 2004:123, supra 2, page 12.

<sup>270</sup> SOU 2004:123, supra 2, page 13.

<sup>271</sup> LYHS, 4:2, 1-6p, supra 256.

<sup>272</sup> Prop. 1981/82:60, page 12.

<sup>273</sup> LYHS, 4:3, supra 256.

had been proven to work through experience and science.<sup>274</sup> Through major political and social changes, this continued until the Swedish Medical Association in 1951 adopted the ethics code *Codex Ethicus Medicorum Svecorum*. It was stipulated in this Codex that the practitioner should always seek to expand his knowledge<sup>275</sup> – a much less conservative standpoint than the older version. In the Doctoral Code of Ethics of 2002, it is stated that the medical practitioner, to the best of his abilities, should *contribute* to scientific progress. This, then, implies that medical practitioners are not tied to existing scientific knowledge, contrary to the word of the law, where it is an imperative and binding rule for all Health Care Personnel.

The term “Science and Verified Experience” is very vague and it is difficult to find any definitive explanation of it. There is no preparatory work that can be found to the 1829 Doctoral Code of Conduct, where the term was first mentioned, which can be of guidance. The term was not analysed nor described in any preparatory documents to the laws surrounding it. Closest is an answer in the form of a letter written to an individual medical practitioner in 1976 who questioned the term, in which the National Board of Health and Welfare stated that it is necessary that a treatment fulfils the criteria of *both* being scientific and referable to verified experience - not one or the other.<sup>276</sup>

According to The National Board of Health and Welfare, the meaning of *Science and Verified Experience* is determined at a given point in time by documented research. The National Board of Health and Welfare, and, if necessary, an administrative court, decide whether a treatment is scientific and in accordance with verified experience.<sup>277</sup>

It is understood by many that, on account of the way the law is written, licensed Health Care Personnel are not permitted to be engaged in Complementary medicine. This has also been expressed in rulings of the courts.

In one case from the Swedish Supreme Administrative Court<sup>278</sup>, a licensed physiotherapist (one of the 17 protected professional titles) had a sign outside her practice which read “licensed physiotherapy, reflexology and Zonotherapy<sup>279</sup>”. She no longer practiced physiotherapy, but stated she wished to show that she had “genuine medical proficiencies”. The National Board of Health and Welfare maintained that one cannot be a Licensed professional and thus work in accordance with the demands of conscientious care according to Science and Verified Experience and simultaneously devote oneself to Complementary treatment methods. The physiotherapist was given a disciplinary warning.

The same attitude can be found in another case from the same year regarding a licensed nurse<sup>280</sup>, working with Zonotherapy, Acupuncture and natural therapies.

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<sup>274</sup> Läkarens skyldighet att ”åt sjuk, som af honom vårdas, meddela de råd och, så vidt möjligt är, efna den behandling, som den sjukas tillstånd fordrar och som med vetenskap och bepröfvad erfarenhet öfverensstämmer”, Eklöf, M., *Vetenskap, etik och medicinsk pluralism*, supra 121, page 214.

<sup>275</sup> *Codex Ethicus Medicorum Svecorum* in Svenska Läkartidningen 1952:49:1-3.

<sup>276</sup> Prop 1993/94:149, page 65.

<sup>277</sup> Gullberg, A.K., *Lagen, alternativmedicinen och den behöriga hälso- och sjukvårdspersonalen, Vård 2002(2)*, page 42.

<sup>278</sup> RÅ 1998 ref 41 I.

<sup>279</sup> See Definitions, supra page 8.

<sup>280</sup> RÅ 1998 ref 41 II.

She gave herself the professional title “nature therapist”. The National Board of Health and Welfare reported her, since they found this to stand in contrast to Science and Verified Experience, it was unacceptable for her to keep her license as a nurse when she was working with alternative remedies, and that she should have her license revoked. The license is society’s mark of quality and she was using unscientific and uncontrolled methods. She replied that she found herself to be acting in accordance with Science and Verified Experience and that either way, her patients came to her as a nature therapist and not as a nurse. The Administrative Appeals Court<sup>281</sup> found her to be “obviously unsuitable to exercise a career within the Health Care system”. Her license was revoked. She appealed to the Supreme Administrative Court<sup>282</sup> where it was stated that the legal situation regarding Licensed practitioner’s right to practice alternative methods was unclear. Since the coming into force of the Health Care Act, there is reason to believe, however, that the legal space for this kind of practice has diminished, as the Health Care Act expresses a more rigid demand for quality. It was repeatedly stated by the court that the legal situation is uncertain and that a ruling is difficult to make. In this particular case, the court found that the defendant could not be seen as obviously unsuitable and the ruling of the lower court was reversed.

A decision taken by the National Board of Health and Welfare in 1975, concerning a doctor using the Natural remedy Iscador, is elucidatory with regard to what Licensed practitioners are authorized to do. The Board found that it cannot be judged to be wrong or negligent when a doctor uses Natural remedies in addition to acceptable treatment, provided always that they have no side-effects.<sup>283</sup>

Some therapeutic methods are not to be regarded as alternative since they are used solely by Health Care Personnel, whilst other methods arose in the alternative area. In some cases, a method is used in different manners within the established and alternative care sectors. The textbook example is Acupuncture, where, since 1982 it is acceptable for Licensed practitioners to use Acupuncture in alleviation of pain. The Acupuncture used in established Health Care is founded on Conventional medicines’ physiology and diagnostics. Alternative Acupuncture, on the other hand, rests upon the traditional Chinese medical explanation systems including concepts such as life energy (qi) and yin/yang. This type of Acupuncture not only attempts to relieve the symptoms, but also aims to balance the general energy in the body.<sup>284</sup>

The point of having this demand for science is that every Licensed practitioner should use the proficiencies and way of thinking taught him during his education.<sup>285</sup> Sweden does not, unlike Norway and Denmark, for example, have a national research institute dealing with alternative and Complementary medicines. There is a restricted amount of research done on the subject at the national universities. The Karolinska Institute, and the Universities of Linköping and Örebro have shown some interest in starting comprehensive courses.<sup>286</sup> The existing courses are, however, limited.

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<sup>281</sup> The Swedish Administrative Court of Appeal, Kammarrätten.

<sup>282</sup> The Supreme Administrative Court, Regerings rätten.

<sup>283</sup> SOU 1989:60, supra 12, page 60.

<sup>284</sup> Id., page 66.

<sup>285</sup> SOU 2004:123, supra 2, page 77.

<sup>286</sup> SOU 2004:123, supra 145, page 45.

The insistence on Science and Verified Experience is to distinguish medical methods which are tolerated from those which are respected. However, what is seen as science is not clearly defined.

### 3.2.2. The products

On July 1<sup>st</sup>, 1993 a new Medicinal Products Act<sup>287</sup> came into force, as a result of adjustment to the EC regulations in the Medicinal products area. The act includes regulations regarding Natural remedies and Homeopathic products, though the latter are not regarded as “medicinal products”, but rather as “other products” in Sweden.<sup>288</sup> The notion “Natural remedy”<sup>289</sup> was introduced in Sweden at the same time, replacing the older nomenclature of “natural product”<sup>290</sup> and indicating the stricter demands placed on Natural remedies. In spite of the new Act having come into force, the older “natural products” continue to be available on the market during a transitional period, until the MPA has completed the review of them.

#### 3.2.2.1. Natural remedies

Natural remedies must be suitable for self-medication in accordance with national tradition or with tradition in countries close to Sweden with respect to drug usage, meaning that they are to be used for common symptoms not calling for a medical practitioner’s attention. The demands on the active ingredients and the suitability for self-care must be fulfilled for approval as a Natural remedy to be granted.

The question of suitability for self-care is discussed in *Swedish Bioforce v the Medical Products Agency*.<sup>291</sup> In this case, the Medical Products Agency sought to remove the Natural remedy “Crataegimin” from the Swedish market on public health grounds. The preparation was not seen as suitable for self-care, and it was therefore the viewpoint of the MPA that it should be classified as a Medicinal product. Bioforce argued that crataegus preparations have a tradition of more than 35 years of well documented use in both Sweden and countries with traditions close to Sweden, and that as yet there are no reports on harmful or negative effects. According to Bioforce, the restrictive measures taken by the Medicinal Products Agency were in breach of the general principle of mutual recognition, and an infringement of Art 28 EC of the Treaty. Within the EU there was at the time work to facilitate approvals and complete the harmonisation with regards to Natural remedies, and it was Bioforce’s view that the MPA was acting in direct opposition to this work. The court found that the approval of Crataegimin was an internal matter to be resolved through national regulations. According to the Code of Statutes of the MPA, only products suitable for self-care can be approved as Natural remedies.<sup>292</sup> The product in question was, according to Bioforce, “traditionally used

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<sup>287</sup> Läkemedelslag (1992:859).

<sup>288</sup> [www.mpa.se](http://www.mpa.se) (August 2005).

<sup>289</sup> *Naturläkemedel*, literally: nature medicinal product.

<sup>290</sup> *Naturmedel*, literally: nature product.

<sup>291</sup> Case nr 44-03 of 11 April 2003, Länsrätten i Uppsala län, *Svenska Bioforce v Läkemedelsverket*.

<sup>292</sup> LVFS (Medical Products Agency's Code of Statutes) 1995:18, Published on 2 November 1995, Medical Products Agency's guidelines on authorization to place natural remedies on the market

for a nervous heart as established by a doctor”<sup>293</sup>. The judgement made by the MPA that the product might mask the symptoms of a non-diagnosed cardiac insufficiency was found to be within reason and the complaint was denied. The case has been appealed, Bioforce being of the opinion that this is in breach of the notion traditional herbal medicinal product<sup>294</sup> as well as of Article 28 of the Treaty.

A Natural remedy is a Medicinal product in which the active ingredient or ingredients derive from natural sources, have not been processed too highly and consist of part of a plant or animal, bacterial culture, mineral, salt or salt solution.<sup>295</sup> Good manufacturing practice is required, that is to say good manufacturing quality and safety. In addition, research or documentation that supports the claim that the Natural remedy has the intended effect is required. The demands for efficacy are, however, substantially lower than those for conventional Medicinal products, this because of the idea that Natural remedies are part of a well established tradition.<sup>296</sup> Efficacy and safety can be substantiated in two ways:

*Either*, and most commonly, reference can be made to medical literature documenting a well established/traditional use in Sweden or in countries with similar medical traditions (assuming that the products’ manufacturing, extract production, composition, dosage, and usage is comparable to the product described in the literature)

*Or* it can be substantiated by scientific studies, as for conventional Medicinal products. The total number and severity of reported side effects are considered when assessing the safety of the product.<sup>297</sup>

Thus, it is possible to make a general efficacy and safety judgement with reference to scientific literature. This is done through critically evaluating reports on the number of treated cases, used dosage and reported side-effects. If this type of data does not exist, the manufacturer must show that the product is safe through the same type of scientific studies as conventional products: pharmacological, toxicological and clinical studies.

If the manufacturer in any way has deviated from the traditional use of the Natural remedy by using, for example, a new dosage or some form of improvement, modern product specific documentation is needed in order for an authorisation to be given.<sup>298</sup> An authorisation is valid for five years, and can be renewed for five year periods.<sup>299</sup> This ensures that the manufacturer is forced to see that the product is always in conformity with the latest medicinal discoveries.

With regard to the marketing of Natural remedies in Sweden, the information that follows the marketing must be current (up to date), objective and balanced, and it may not be misleading.<sup>300</sup>

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<sup>293</sup> Case 44-03, *Svenska Bioforce AB v Läkemedelsverket*

<sup>294</sup> Dir 2004/24/EC, supra 222

<sup>295</sup> LVFS 1995:18, 1§ p2

<sup>296</sup> Färnlöf, Å. & Tunón, H., *Naturläkemedel 2000*, Hälsokostrådets Förlag 2000, page 13.

<sup>297</sup> Eklöf, M., & Kullberg, A., *Komplementär medicin, Forskning, Utveckling, Utbildning; en rapport på uppdrag av Landstingsförbundet*, Tema Hälsa och samhälle, Linköpings universitet 2003, page 13.

<sup>298</sup> Färnlöf, Å. & Tunón, H., *Naturläkemedel 2000*, supra 296, page 12.

<sup>299</sup> Läkemedelslag, supra 287, 6§, 3st.

<sup>300</sup> Id., 21§, 2st.

In contrast to conventional Medicinal products, which are only sold in Apoteket, the trade of Natural remedies is open. They are sold via health food stores, in general sales, through therapists, and by mail order, as well as at Apoteket.

### 3.2.2.2. Homeopathic products

The Medicinal Products Act is only to a limited extent applicable to Homeopathic products.<sup>301</sup> It defines the fundamental criteria, which must be fulfilled for registration of a Homeopathic product to be allowed<sup>302</sup>: a product prepared according to a recognised homeopathic method which

- makes no therapeutic claims;
- is for oral or external use;
- is sufficiently diluted to guarantee its safety;

Homeopathic products which fulfil these criteria must be registered with the Swedish Medical Products Agency (Läkemedelsverket) in order to be sold on the Swedish market.<sup>303</sup> The Medical Products Agency assesses the products' quality, safety and labelling. However, no valuation on the *efficacy* of the product is made, and no indication of effect is allowed on the marking of the products or in the package insert.<sup>304</sup>

Products for internal use cannot be registered as Homeopathic products unless they are to be administered orally. According to Swedish tradition, products administered through the skin, mucous membrane, and nostrils (amongst many other listed manners of administration) are considered to be products for internal use and can not therefore be registered as Homeopathic products.<sup>305</sup>

The homeopathic registration scheme, implemented under European Directive 92/73 EEC, is a simplified regulatory procedure, whereby products are assessed for their quality and safety and can then be marketed without specific medical claims. The simplified registration scheme thus enables a rapid introduction of new Homeopathic products onto the Swedish market. Registration under the scheme is compulsory only in respect of homeopathic products new to the Swedish market. Homeopathic products that were on the market before 1 July 1993 continue to be available by virtue of a specific regulation, provided that they have applied for registration with the Medical Products Agency.<sup>306</sup>

### 3.2.2.3. Distribution of Medicinal products

According to Swedish national legislation, retail trade in non-prescription and prescription medicinal preparations can be engaged in only by the State or by legal persons over which the State has a dominant influence.<sup>307</sup> Medicinal products include all products defined by the Medicinal Products Act. The company entrusted

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<sup>301</sup> Id., 2§, 3st.

<sup>302</sup> Id., 2§ 4st.

<sup>303</sup> LVFS (Medical Products Agency's Code of Statutes) 2003:2, Instructions regarding amendments to the Medical Products Agency's provisions and guidelines (LVFS 1997:9) on the registration of certain homeopathic products, 2:1.

<sup>304</sup> Id., 3:2.

<sup>305</sup> Id., *General advice on chapter 1*, page 2.

<sup>306</sup> LVFS (Medical Products Agency's Code of Statutes) 1997:9, The Medical Products Agency's provisions and guidelines on the registration of certain homeopathic products, Transitional stipulations.

<sup>307</sup> Lag (1996:1152) om handel med läkemedel m.m., 4§.



to cover the retail trade is Apoteket, where the Swedish State has a majority holding of two thirds of its capital.<sup>308</sup> Apoteket is required under the “1996 agreement” to, amongst other things, organise a nationwide system for the distribution of medicinal preparations and to supply all prescription and non-prescription medicinal preparations.

The sale of Natural remedies is done both through Apoteket and other channels, whereas Homeopathic products were no longer sold via the State pharmacies after 1974.<sup>309</sup>

Homeopathic products are instead sold through health food stores, in general sales, by therapists and via mail order. Wholesale trade in Homeopathic products may only be pursued by those given permission by the Medical Products Agency. This includes all and any activity regarding acquisition, possession, export or delivery of Homeopathic products - except retail trade, that is to say sale/distribution to the public.<sup>310</sup> Only Homeopathic products registered in Sweden may be sold in Sweden.<sup>311</sup>

It is interesting to note that Norway does not have a State monopoly, but demands that homeopathic remedies must be sold through pharmacies.<sup>312</sup>

In the recent *Case C-438/02 “Hanner”*<sup>313</sup>, where judgment was given on 31 May 2005, the question arose whether Krister Hanner, in marketing non-prescription Medicinal products, had been in breach of the Swedish rules reserving retail sales of medicinal preparations. In his defence, Mr Hanner contended that those rules establish a State monopoly contrary to Articles 28, 31 and 43 of the Treaty. The Court found that the “1996 Agreement” does not ensure the exclusion of any discrimination against medicinal preparations from other Member States<sup>314</sup> and that Article 31(1) of the Treaty precludes a sales regime which grants an exclusive retail right and is arranged as was the sales regime of Apoteket.<sup>315</sup>

The court’s judgement only answers the matter put to the question; that is if the present State monopoly is discriminatory. Apoteket has consented to the former organisation of the company having been in breach of European law, but contends that, having now undergone organizational changes; it is once again in line with European demands and the Swedish State monopoly is lawful under EU law. The question remains open.

It is interesting to note that Mr Hanner was acquitted in the criminal proceedings in the District Court, but that the prosecutor has now appealed the case.<sup>316</sup>

### 3.2.3. Summary

**Caregivers** in Sweden can be divided into two categories; Health Care Personnel and Paramedicinal practitioners. The legal rights and duties of these two

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<sup>308</sup> ECJ, C-438/02, *Krister Hanner*, 31 May 2005, [2005] ECR n.y.p.

<sup>309</sup> Eklöf, M., *Kvacksalveriet - hett debattämne under hela seklet*, supra 254, page 120.

<sup>310</sup> LVFS 2003:2, supra 303, *General advice on chapter 5*, page 9.

<sup>311</sup> *Id.*, page 9.

<sup>312</sup> [www.homeopati.no](http://www.homeopati.no), August 2005

<sup>313</sup> Case C - 438/02, supra 308.

<sup>314</sup> *Id.*, paragraph 48.

<sup>315</sup> *Id.*

<sup>316</sup> *Sydsvenskan*, 2005-07-26, s. A17 ”Dom om Apotekets monopol överklagas”.

groups differ to a large extent. Only Health Care Personnel may treat certain illnesses and conditions including cancer, contagious diseases, diabetes, and epilepsy amongst others. Health Care Personnel must work in accordance with Science and Verified Experience, the definition of which is rather uncertain. There has been discussion as to the possibility of introducing a register for Paramedical practitioners, though this has not yet been implemented.

**Products:** The Medicinal Products Act of 1993 came into force as a result of adjusting to EC regulations in the Medicinal products area. The Act regulates Natural remedies but only concerns Homeopathic products to a limited extent.

*Natural remedies* must be suitable for self-medication in accordance with national tradition or tradition in countries close to Sweden with respect to drug usage, meaning that they are to be used for common symptoms not calling for a medical practitioner's attention. The requirements regarding the active ingredients and the suitability for self-care must be fulfilled in order for approval as a Natural remedy to be granted.

*Homeopathic products* are products prepared according to a recognised homeopathic method which make no therapeutic claims, are for oral or external use and are sufficiently diluted to guarantee their safety. The Medical Products Agency assesses the products' quality, safety and labelling. However, no evaluation of the *efficacy* of the product is made.

*Conventional Medicinal products*, whether on prescription or traded over the counter, are reserved for Apoteket – the Swedish monopoly, whereas Natural remedies and Homeopathic products may be sold more freely.

## 4. Analysis

As stated in the introductory chapter, the purpose of this paper is to examine whether the Swedish attitude towards Complementary medicines is defensible in a European perspective. The presentation has demonstrated that quackery or non-tolerated activities have never been accurately defined in the past. In order to discover the non-tolerated activities, it has been necessary to investigate the respected and tolerated activities. What does not fall under these categories can be regarded as non-tolerated. In fact, the legislation is precise with respect to respected, but allows a fairly wide discretion with respect to what can be regarded as tolerated. Only very few practices, bordering on fraud and deception, come clearly within the non-tolerated quackery notion.

### *History as an explanation for the present situation*

An exposition of the historical events leading up to the present offers a background understanding of the medicinal situation in Europe today. Medicine used to be atomized, a jumble of patient-doctor transactions. Practitioners were mainly self-employed. Today, medicine has turned into the proverbial Leviathan, comparable to the military machine, and in many cases no less business oriented than the large corporations.<sup>317</sup> History presents itself as an explanation for the Swedish legal situation and most important, peoples attitudes, as they are today.

Licensed medicinal practitioners have had the backing of the State since early times, and their view on anything outside of their profession has tended to have been very condescending. The acceptance of Paramedicinal practitioners has never truly existed in Sweden, primarily as a result of State monopolies on the treatment of disease. During more than 220 years the law – even though perhaps not adhered to – forbade the practice of medicine by anyone not licensed. Even with the coming into force of the law of 1915, which allowed for Paramedicinal practitioners to operate, the attitude towards Complementary medicines was clear. The law was dubbed the *Quackery Law*. The Medicinal Review raged over the incompetence of “quacks”, and the doctoral guild in large never came to accept - or even tolerate - the *others*, even though the demand for their services has grown continually.

The situation in other European countries was often different. Complementary medicine was taught in universities and licensed Health Care Personnel often practiced Natural remedies and Homeopathic ideas. This has remained the case.

The result is that the general attitude towards Paramedical practitioners, alternative and Complementary medicine in Sweden today differs from that of many of the other Member States of the European Union.

### *Respecting, tolerating and non tolerating societies*

Inclusive healthcare systems, such as the German, acknowledge certain Complementary medicines, but may not have integrated them completely in all aspects. There may, for example, lack a nationally accepted education system or control of the products.<sup>318</sup> According to a study from 2002, 73% of all adult Germans have experience with Natural remedies, and there is presently a

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<sup>317</sup> Porter, R., *The greatest benefit to mankind* supra 5, page 628.

<sup>318</sup> Falkenberg, T., et al., *Komplementärmedizin*, supra 170, page 53.

Government programme encouraging comparative studies of therapies in the treatment of conditions where Complementary medicines are normally used.<sup>319</sup>

Great Britain is the only European country which has public hospitals with Complementary medicines, for example the Royal London Homeopathic Hospital.<sup>320</sup> These are indications of health care systems where Complementary medicine is respected.

Sweden is, on the other hand, an example of a healthcare system, where only Conventional medicine is accepted and respected, and Complementary medicines have at times not been tolerated and are still not officially acknowledged.<sup>321</sup>

We have seen that the Swedish licensed medical practitioners have a condescending view on anything not practiced “in accordance with Science and Verified Experience” – an interesting term in itself. This attitude is plain to see in the Medicinal Review where demands to end “quackery” can be heard throughout the century.

### ***European unity requires changing attitudes***

The disparate views in the different European States, of course, cause problems when trying to legislate in the Union. Even within the Community, attitudes differ largely. EU legislation tends to be in favour of complementary treatment. Natural remedies are basically treated as Conventional medicines and homeopathics come under similar regulation.

The European Court of Justice has shown a very lenient attitude towards Complementary medicine and its professional actors and the interpretation of *medicinal service* has been broadened to include Paramedicinal practitioners and their activities.<sup>322</sup> The focus in Europe is on the purpose of the activities of the Caregivers.

Swedish negativity has been forced to bow to Europe and incorporate more tolerant legislation into its national rules governing Complementary medicines, yet it is obvious that the attitude held by the Licensed practitioners is not one that will change easily. The attitude is continually given support<sup>323</sup>. The Swedish public is, none the less, increasingly turning to Paramedicinal practitioners.

### ***Non-discrimination and the principle of fiscal neutrality***

While it is true that the Member States themselves may decide in national legislation restriction of the performance of certain medicinal tasks<sup>324</sup>, it must be done in a non-discriminatory manner.

Furthermore, it has been judged that when Paramedicinal practitioners *are* entitled to perform these tasks, they are entitled to the same conditions as Health Care Personnel. For example, the same tax exemptions, under the principle of fiscal

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<sup>319</sup> Eklöf, M., & Kullberg, A., *Komplementär medicin*, supra 297, page 64.

<sup>320</sup> Id., page 61.

<sup>321</sup> Falkenberg, T., et al., *Komplementärmedicin*, supra 170, page 53.

<sup>322</sup> Case C-45/01, supra 202.

<sup>323</sup> See for example article in the Lancet, below note 338.

<sup>324</sup> Case C-61/89, supra 198, and Case C-108/96, supra 206.

neutrality, should apply for all persons practicing medical care, including persons who are not doctors but who provide paramedical services.<sup>325</sup>

Question now arises why the principle of fiscal neutrality as defined in law and set in case-law is applicable to Health Care Personnel but not health care products. Medical products in Sweden must be registered, production conditions are subject to inspection, but are exempt from tax. Foodstuffs are not subject to registration or inspection, but must on the other hand pay 12,5% value added tax, 50% less than normal VAT. Homeopathic products must be registered, are subject to inspection and, since they fall outside the scope of both foodstuffs and medical products, they are subjected to a 25% value added tax.. Homeopathic products in Sweden are thus under a heavy burden. As a consequence, producers of homeopathics are today choosing to market their products as foodstuffs to avoid falling under medical legislation. This way, they avoid the registration costs while simultaneously cutting their VAT costs in half. Whether this consequence is intended is questionable. The principle of fiscal neutrality rather supports no value added tax on Homeopathic products.

### *Homeopathic products and their administration*

The criterion in Swedish national law that Homeopathic products must be for oral or external administration has its correspondence in EU law. The interpretation of this criterion as set out in the Community Code, however, greatly differs between the Member States. Swedish practice allows a very limited type of administration manners. This is in line with EU law, since in the absence of a clear definition, each Member State is free to regulate as they wish.<sup>326</sup> On the other hand, Germany, for example, has chosen to interpret the criterion differently. A larger number of methods of administration are accepted which do not fall in under the literal wording of the EU criterion, yet also Germany may interpret as they see fit. There might be reasons for the authorities to consider the reasons behind limiting the administration forms for the Homeopathic products.

In addition, it is illegal in Sweden to have any form of indication or description of usage on the labelling or inserts of homeopathics. The question is how far this prohibition reaches. The Swedish interpretation is strict. No claims, which has full support in EU law. But does this prohibition extent to any information - for example that a certain type of product is traditionally used for certain conditions? Where should the line be drawn?

Question arises as to what impact these different interpretations may have on the EU market. If the Swedish interpretation is stricter than other Member States, such could be regarded as a measure having an equivalent effect of a quantitative restriction in breach of Article 28 of the Treaty. It should be reminded that as long as the information on the products are not liable to mislead a reasonably well-informed consumer, it should not present a problem.<sup>327</sup>

A more narrow interpretation of a rule is not necessarily an incorrect one. The fact that one Member State imposes less strict rules than another does not mean that the latter's rules are disproportionate and hence incompatible with Community law. "The mere fact that a Member State has chosen a system of protection different

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<sup>325</sup> Case C-45/01, supra 202.

<sup>326</sup> Case C-108/96, supra 206.

<sup>327</sup> Case C-221/00, supra 246.

from that adopted by another Member State cannot affect the appraisal as to the need for and proportionality of the provisions adopted”.<sup>328</sup>

The outcome of a ruling regarding these discrepancies is uncertain, but certainly is necessary in order to ensure the functioning of the internal market.

### ***Science and Verified Experience***

The existing contradictions are not only on a cross-national level, but on a purely internal, national level as well. In Swedish law, the expression “Science and Verified Experience” is a key expression in defining Health Care Personnel. The term has its roots in documents dating almost 200 years back. The notion behind the term is typical of modernism, with the idealisation of science and new thought. The wording of the term as such is not optimal. How can experience be anything other than verified? The essence of experience is that it has been verified. Though this is only semantics, it calls into question the rationality behind the expression.

There is no clear definition of “Science and Verified Experience”, as explained above<sup>329</sup>. The National Board of Health and Welfare has in an unofficial attempt to define the expression stated that it is necessary that a treatment fulfils the criteria of *both* being scientific and referable to verified experience - not one or the other.<sup>330</sup> This is, however, difficult to comply with, since new methods of treatment never comprehend experience, just as certain methods have prolonged clinical experience of the method without a scientific explanation as to why the results are as they are.

This makes for an arbitrary and changeable term, which creates insecurity in Licensed practitioners as to what is acceptable and not. They therefore choose not to use anything other than Conventional medicine. In fact, Health Care Personnel are not allowed to use Complementary methods, though one cannot point to any specific stipulation which prescribes this result. This attitude stems from Swedish case-law.

Even if medical care is to be given in accordance with Science and Verified Experience by Health Care Personnel, it stands to reason that it would be impossible to make the same demands on everybody active within the health care system. Different education and experience make for modulated demands on individuals. The individual care giver’s actions in a given case must be judged in the light of education, competence and experience.<sup>331</sup>

What is also interesting to note is the fact that Swedish Health Care Personnel get very little, if any, education on Complementary products, even though they are approved as Medicinal products. In demanding that the Swedish professionals only work with therapies and products on which they have experience, the legislator ensures that the products are not used by the Health Care Personnel. This appears to be an indirect obstacle in breach of Article 28 of the Treaty.

### ***The Paramedicinal practitioners***

The *other* Caregivers in Sweden, the Paramedicinal practitioners, may not, as we have seen, treat certain groups of patients nor certain conditions. The conditions

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<sup>328</sup> Case C-108/96, supra 206, paragraph 34.

<sup>329</sup> See 3.2.1.4.

<sup>330</sup> Prop 1993/94:149, page 65.

<sup>331</sup> SOU 1989:60, supra 12, page 50.

omitted from their care in the fourth chapter of LYHS, the *Quackery law*, include illnesses such as cancer, contagious diseases, diabetes, epilepsy, and illnesses occurring in association with pregnancy or birth. These are all potentially fatal conditions, and the demand for Licensed practitioners and Health Care Personnel's monopoly on the treatment of these conditions are understandable. These patients may be in a desperate and dejected state and willing to try almost anything to cure their condition. The attempt to retain them in conventional care is understandable, even if there is a risk of excluding services which might be helpful.

The Paramedicinal practitioners may not use general anaesthetics or local anaesthetics by injection, hypnosis or treatment using radiological methods. It is explicitly prohibited to give advice or directions without meeting with the patient personally. In addition, unlicensed caregivers may not try out or supply contact lenses.<sup>332</sup> The treatment of children under the age of eight is forbidden.

The *Grandvision-case*<sup>333</sup> prohibited opticians from carrying out certain optical examinations which were restricted to doctors. In absence of specific Community rules, the Court found that each Member State is free to regulate the practice of a profession on its territory for reasons relating to the protection of public health.

The exclusion of the treatments in chapter 4 of LYHS is therefore compatible with European law. In addition, the case shows that the exception of contact lenses in the 2<sup>nd</sup> paragraph is an acceptable derogation in the light of the public health protection provided in Art 152 of the Treaty. The main responsibility in the field of public health lies, as stated earlier, with the Member States.<sup>334</sup>

### ***Defining the medical actors***

A 2004 Government's Official Report<sup>335</sup> suggests the registration of practitioners of Complementary medicine with the objective of increasing patient safety. Registered practitioners would have to have a basic medicinal education, and only members of the professional organisations within the alternative and Complementary medicinal sphere would be allowed to register. The registration would, however, not be a prerequisite for being allowed to practice Complementary medicine. Consequently, Paramedicinal practitioners will be divided into two subcategories;

1. the Registered Paramedicinal practitioners, and
2. the Unregistered Paramedicinal practitioners.

Such a division may have a larger impact than thought. Not only would it ensure the public's safety in general, but perhaps play the role of a semi-license, showing society's acceptance of Paramedicinal services. The division might also shift the condescending view found among Health Care Personnel towards all Paramedicinal practitioners, to focus on the unregistered Paramedicinal practitioners.

### ***“Quackery” and monopoly***

There are many definitions of quackery, including the prevalent one defining it as the unauthorized practice of the profession of doctor. The more condescending

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<sup>332</sup> LYHS, supra 256, 4:2, 1-6p.

<sup>333</sup> Case C-108/96

<sup>334</sup> Opinion of Advocate General Mischo, Case C-108/96, supra 187, paragraph 58.

<sup>335</sup> SOU 2004:123, supra 145.

meaning: to consciously and fraudulently give oneself out as being able to treat and cure without that being the case, is not the official - but very often explicit - meaning.<sup>336</sup> Quackery is often associated with harm. The term has not remained fixated in meaning; it has fluctuated in just the same way as the reasons given for the superiority of medical science have varied, in step with the changes undergone in society at large. This being true, one might ask oneself if it is not time to remove the reference in the civil law book register to the *Quackery law* with a cross-reference to chapter 4 of LYHS.

At the time of writing, the effects of the ruling of the Court with regards to the Swedish national monopoly on the retail of medicinal preparations (*Hanner*) have not been finally decided. Will the judgement have an impact on the Swedish attitudes towards Complementary medicines if private pharmacies advertise and bring forth the products in a different manner than the State has done? In addition, the mail-order sales of Medicinal products via virtual pharmacies will, it can be assumed, continue to increase, jeopardising the continued existence of traditional pharmacies not living up the demands of the consumers.

An interesting view point on the difficulties regarding the Complementary products is, according to the former Chairwoman of the Swedish Committee on Alternative Medicine (KAM), Susanne Nordling, the fact that the Health Care Personnel do not wish to use the Complementary medicinal products since they have not been proven to work. As soon as Homeopathic products, Natural remedies and food stuffs are proven to work they are classified as Medicinal products and disappear from the Complementary therapists' table – a Catch-22 situation.<sup>337</sup>

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<sup>336</sup> Eklöf, M., *Kvacksalveriet - hett debattämne under hela seklet*, supra 254, page 114.

<sup>337</sup> Forskning och Framsteg, Nr 7 2002, page 15.



## 5. Conclusions

Whether a therapeutic method is viewed as Conventional or Complementary depends on what historical, geographical and cultural perspective one has. A method considered Complementary in Sweden may be officially accepted and established as Conventional in other parts of the world. The boundary between the two has varied throughout history. For centuries, there was no difference between Licensed practitioners' and Paramedicinal practitioners' methods of treatment. Parallel to medicinal science's evolution and thanks to increased regulation in the health care arena during the 1900s, the boundary has become sharper.

In a recent issue of *the Lancet*<sup>338</sup>, a world leading medical journal, Homeopathy is written off as being effective only as a result of the placebo effect. Is this the beginning of the demise of Homeopathy – or is this yet another manifestation of the negative attitude towards complementary remedies for which Licensed practitioners are known? History has shown us the repeated attempts of Licensed practitioners and society to stifle the activities of Paramedicinal practitioners. It is likely that this now effort will lead to dramatic results because it seems that Licensed practitioners are often misinterpreting the interests of their patients. The Paramedicinal practitioner is skilled in meeting the patient, giving the patient time and hope. The Homeopathic products prescribed are at least not harmful and the placebo effect is not to be neglected. The Complementary methods often emphasize the subjective feeling of the patient, rather than scientifically proven physical changes. Such subjective effects are not measured by the Licensed practitioner, but may be just as important to the patients. Complementary medicines have throughout history showed remarkable results.

The question of registration of Paramedicinal practitioners has been investigated in the Government Official Report (SOU) 2004:123<sup>339</sup>, a proposal which might be seen as society's legitimatization of these actors and their therapies. In my mind, registration will ensure the patient's need for protection. Registration might even correspond to a license, which will ensure a certain degree of quality and effectiveness of the care given by the registered Paramedicinal practitioners. I would, however, recommend a few changes in the proposed legislation. Firstly, the report refers to professional practitioners of alternative *or* Complementary medicine. I agree with the Swedish Committee on Alternative Medicine's (KAM) objection<sup>340</sup> that the wording "or" should be replaced by "and/or", since many Paramedicinal practitioners' therapies can be used both as an alternative to Conventional medicine and as a complement to it. Also, the report proposes the Board of education as the authority responsible for the register<sup>341</sup>, which seems unreasonable. The Board of Education has no experience with Complementary medicines, and it stands to reason that the Committee on Alternative Medicine is the most suitable organ for this task, with their more than 20 years of experience of the questions involved in the registration of Paramedicinal practitioners.

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<sup>338</sup> The Lancet, Volume 366, Number 9487, 27 August 2005, found on <http://www.thelancet.com/journals/lancet/article/PIIS0140673605671772/abstract>.

<sup>339</sup> SOU 2004:123, supra 2.

<sup>340</sup> Kommittén för Alternativ Medicin, *Yttrande till Socialdepartementet angående SOU 2004:123*, 2005-05-10, page 1.

<sup>341</sup> SOU 2004:123, supra 2, page163.

In my opinion, Sweden must take a stand on the question and stick to it. Are Complementary medicines accepted or just tolerated?

When discussing the question of acceptance and tolerance with regard to Complementary medicines, it is interesting to bring forth the German sociologist Ulrich Becks' theory on *reflexive modernism*.<sup>342</sup> According to this theory – and in contrast to modernism which advocated a logic of *either-or* – our contemporary times' reflexive modernistic view is founded on an *as well as – principle*. Presently, the patients *either* get Conventional medicinal help *or* have to turn to actors outside of State Health Care. In accordance with the *reflexive modernism* theory, we can no longer allow ourselves to see the medicinal market as homogenous. The time has come where we must develop and *as well as* attitude. Conventional medicine *as well as* Complementary medicines should be available to patients. Sweden can no longer act as a sovereign power vis-à-vis the patients, since European law *as well as* Swedish national legislation governs Health Care.

In accepting these practitioners and their methods in national legislation through registration, society's mark of approval is given, and Swedish society's overall attitude will have changed into an accepting one. If this is the case, then society should perhaps act against the negativity surrounding Complementary medicine exhibited by licensed medical practitioners, through official recognition of their methods, grants for research, and education. A tenable development of health care systems within the Union with regards to Complementary medicines requires research of high quality but also adequate education of both complementary therapists and of Licensed practitioners.<sup>343</sup> Co-operation between the two sectors can only be achieved if there is an increased understanding.

There are many explanations for the increasing interest in Complementary medicine in Sweden. Some argue that Complementary medicine owes its popularity to the fact that it is effective. Conventional medicine has made it possible to successfully treat diseases earlier thought incurable. However, it is also a known fact that Conventional medications can have side effects. Natural remedies have always existed next to Conventional medicines, and one of the reasons that interest has grown in Paramedicinal remedies in today's society is the unwanted side effects of Conventional medicine. The long waiting periods in the State care system is another reason often given - the growing discontent with the organisation of modern health care. Hospitals are large and impersonal, and licensed medical practitioners do not have enough time for each patient. There has been an increase in specialisation and the individual doctor specializes in one part of the human to be repaired, giving him a lesser knowledge of the social and personal reality which may have caused the illness in the first place. Where Licensed practitioners may focus on the disease at hand, the complementary methods focus on the patient as a whole. A first examination with a therapist practicing Complementary medicine usually takes no less than an hour. This is then to be compared with the 15 minutes or less that most licensed medical practitioners have at their disposal.<sup>344</sup> The patient leaves with a prescription which may in fact not even be necessary.

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<sup>342</sup> Referred to in Modéer. K.Å., *Religionernas roll i blandade rättskulturer* in Kungliga Humanistiska Vetenskapssamfundet i Lunds Årsberättelse 2004-2005, page 19 ff.

<sup>343</sup> Falkenberg, T., et al., *Komplementärmedicin*, supra 170, page 58.

<sup>344</sup> Forskning och Framsteg, Nr 7 2002, page 15.

Whether the licensed medical practitioners like it or not, it seems that Complementary medicine is becoming more and more incorporated in the consciousness of the public and gaining the acceptance of society at large.

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I'm sick of gruel, and the dietetics,  
 I'm sick of pills, and sicker of emetics,  
 I'm sick of pulses, tardiness or quickness,  
 I'm sick of blood, its thinness or thickness, -  
 In short, within a word, I'm sick of sickness!

Thomas Hood, “Fragement”, 1844