

# **TOWARDS ANOTHER MODEL OF HEALTH AND DISEASE**

**A new perspective on how to achieve  
good health for all across the EU**

**European Committee for Homeopathy  
September 2004**

## **European Committee for Homeopathy**

The European Committee for Homeopathy or ECH is the European association for all statutorily regulated health professionals (medical doctors, veterinarians, dentists, pharmacists, midwives, etc.) in the field of homeopathy, as well as other professionals who can contribute to the development of homeopathy (such as researchers, documentalists and patients' organisations).

Its aims are:

- To promote and defend the quality of the science of homeopathy;
- To defend, by all legal means, the practice of homeopathy;
- To promote research in homeopathy;
- To assist all the people it represents in their local activities;
- To promote the harmonisation of the practice of homeopathic medicine in Europe;
- To represent both individuals, as well as local, regional and national organisations throughout Europe which share the same aims.

To date 33 homeopathic doctors' associations in 24 European countries are affiliated to the ECH, which means a coverage of more than 90 % of all 12,000 homeopathically trained doctors in Europe. In addition, most homeopathic veterinarians and dentists in the European Union are affiliated. The ECH comprises various subcommittees working in different fields, such as education, politics, pharmacology, documentation, research, provings, patients/users etc.

The ECH is a member of the Health Policy Forum at DG SANCO.

### **Reason for this report**

This report is the ECH's answer to Commissioner Byrne's request to formulate what Europe needs to do to achieve good health for all across the EU.

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## **Executive summary**

Biomedicine, the predominant medical model in Europe, which is intrinsically interventionist, has earned an impressive reputation, when it comes to emergency medicine, trauma, the treatment of acute or life threatening conditions or conditions with irreversible tissue damage, and, in addition, the possibilities of medical technology — whether the use of miniature robots for surgery, genetic therapies, growing replacement organs and tissues. However, Europe is also confronted with ever increasing health care expenditure, an increasing prevalence of chronic diseases and failure of effectively managing them, a huge burden of adverse side effects and mortality due to the toxicity of prescription drugs, and a growing resistance to antibiotics.

Patients are becoming more and more worried about these issues and are, although not giving up biomedicine, increasingly looking for less-toxic and more humane alternatives, especially for chronic illness. Holistic medicine, with its fundamentally supportive nature and its potential to humanise modern medicine and widen its vision beyond disease to health and wellbeing, is much more effective than biomedicine when it comes to restoring the patients' own natural systems for fighting disease and maintaining health with the aid of natural medicines, modification of lifestyle, dietary change and health psychology approaches. Integrated medicine, which as the best of both worlds maximises both safety and choice, provides a new perspective on how to achieve good health for all European citizens.

It is necessary for physicians to broaden their understanding of how different systems within the mind/body interact and fully embrace the evidence demonstrating that taking care of the mental, emotional and spiritual aspects of a patient's life is just as important as correcting physiological derangements, for all these aspects are inseparable. Such notions are based on very sound scientific evidence.

The desirable way forward implies that the Member States and the European Union realize that it should be more responsive to patients' demands. There are a few initiatives to integrate complementary and alternative medicine (CAM) with national health care systems and to expand the knowledgebase on CAM, namely by the WHO and the US and UK governments. The time has come that all EU Member States adopt policies in order to define the role of CAM in national healthcare delivery systems. All the major CAM systems approach illness first by trying to support and induce the self-regenerating process of the person. If recovery can occur from this, the likelihood of adverse effects and the need for high-impact, high-cost intervention is reduced. It is this orientation towards self-healing and health promotion — salutogenesis rather than pathogenesis, or improving health rather than defeating disease — that makes CAM approaches especially appropriate.

In contrast to the widespread use of CAM among European citizens, to date there has been a negligible amount of funding for research in this area by the European Union and EU Member States. The EU Member States are recommended to provide adequate support for further research on the safety and effectiveness of CAM, through both private and public funding. Without dedicated funds, it will be hard to build the infrastructure for CAM research.

The general recommendations of the Management Committee of the COST B4 Action on Unconventional Medicine (= CAM) in their 1998 report — published by the Directorate Science, Research and Development of the European Commission — are still highly relevant and are awaiting implementation. Implementation would be fully in line with developments in the USA and with the WHO policy.

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## **1. Current situation in European healthcare**

### 1.1 Health care costs

The EU spends an ever-increasing share of its gross domestic product (GDP) on health. Over the last 40 years the growth in health care spending has outstripped that of GDP in all industrialised countries. The OECD health data show that total health care spending rose from around 5% of GDP in 1970 to over 8.4% in 2001. In fact, public health spending grew faster than total health spending until the end of the 1970s (rising from 3.9% of GDP to some 6%). This fact raises questions of long-term sustainability.

### 1.2 Chronic diseases

Over the last few decades, the western European countries have shown a steady decline in or stabilization of morbidity and mortality from communicable diseases. The relation between a higher economic standard on the one hand and hygiene, nutrition, and susceptibility to these diseases on the other is well documented. However, from the mid-sixties a consistent picture of an epidemiological transition from acute infectious diseases towards chronic debilitating illnesses (also called non-communicable diseases) has been obvious. Nowadays chronic diseases represent the bulk of morbidity, disability and premature death in the WHO European Region. These diseases are responsible for 85% of deaths and 75% of the disease burden expressed in DALYs (disability-adjusted life-years) in 2000 in the European Region and are expected to continue to increase (WHO Health report, 2002). In Western European countries the cancer mortality rate, after a 10% decrease between 1988 and 1997, has started to level off in recent years (Van der Wilk, 2004).

According to the WHO Health report 2002, the most prominent non-communicable diseases share common preventable lifestyle-related risk factors such as tobacco, unhealthy diet, alcohol abuse, obesity and reduced physical activity. Psychosocial stress has also been identified as important in the development of chronic disease. Many European Member States lack a national policy, and therefore do not take the action needed to control and prevent chronic diseases (WHO, 2004). The World Health Assembly (WHA) in 1998 recognized the threat posed by chronic diseases and a global strategy for their prevention and control was developed declaring that their prevention and control will be a priority. The WHO has called on all Member States to develop their national policies for chronic disease prevention and control to be guided by the global strategy. The objectives of the WHO global strategy are to map emerging epidemics, to reduce exposure to common risk factors, and to strengthen health care through surveillance, health promotion, disease prevention and effective interventions.

### 1.3. Antibiotics

After their discovery in the 1940's antibiotics considerably reduced illness and death from infectious diseases that are caused by bacteria. However, over the decades virtually all important bacterial infections throughout the world have been becoming resistant especially due to the increasing and indiscriminate use of powerful, broad-spectrum antibiotics to treat common infections, such as ear infections, and the misuse of antibiotics in situations where they are not appropriate, such as treating viral infections like the common cold.

Tuberculosis, gonorrhoea, malaria, pneumonia, meningitis, and sexually transmitted diseases, that are caused by bacteria were once easily treatable with antibiotics but have now become

hard to treat with antibiotic drugs and increasingly deadly due to antibiotic resistance. Antibiotic-resistant ‘super bugs’ cause an estimated 19,000 deaths in the USA each year, compared with a few hundreds of deaths worldwide that have been attributed to SARS (Fisherman<sup>1</sup>). Antibiotic resistance has been called one of the world's most pressing public health problems.

Over the past four decades there has been an explosive increase in allergy and asthma in westernized countries, which is likely to correlate with widespread use of antibiotics leading to alterations of the gastrointestinal microflora (Noverr, 2004). A recent study (Cole Johnson, 2004) has shown that children who receive antibiotics within their first six months of life were three times more likely to develop allergies (to pets, ragweed, grass and dust mites), and in case of broad-spectrum antibiotics even 8.9 times more likely to suffer from asthma.

Approximately 50% of Europe's total consumption of antibiotics is by animals. Treatment of food-producing animals – for important therapeutic, disease prevention or production reasons – with antibiotics that are important in human therapy may present a public health risk by the transfer of resistant zoonotic pathogens or resistant genes from animals to humans via consumption of contaminated food<sup>2</sup>. Resistant bacteria can diminish the effectiveness of antibiotics and demand the use of more expensive or less safe alternatives.

#### 1.4. Drug (in)effectiveness

Not only are antibiotics increasingly ineffective. Dr. Allen Roses, worldwide vice-president of genetics at GlaxoSmithKline (GSK), Britain's giant pharmaceutical company, recently acknowledged at a scientific meeting in London<sup>3</sup> that fewer than half of the patients prescribed some of the most expensive drugs actually derived any benefit from them. "The vast majority of drugs - more than 90 per cent - only work in 30 or 50 per cent of the people," Dr Roses said.

#### 1.5 Adverse drug reactions

The rise of modern medicine has brought with it a brand new group of diseases termed ‘iatrogenic’, i.e. doctor-related, diseases. Lazarou (1998) analyzed 39 prospective U.S. studies to determine the incidence of serious and fatal adverse drug reactions<sup>4</sup> (ADRs) to prescription drugs in patients admitted to hospital or developing adverse reaction while in hospital and estimated that in the USA iatrogenic disease is responsible for as many as 100,000 deaths (a death rate of 0.32%, i.e. 0.13% incidence of fatal ADRs in patients admitted to hospital, and 0.19% in patients developing and ADR while in hospital) annually, making such drugs the fourth to sixth leading cause of death in the USA. Extrapolation of the USA figures to the 25-member European Union would result in as many as 150,000 deaths per year. These deaths

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<sup>1</sup> Director of the department of healthcare epidemiology and infection control at the University of Pennsylvania Medical Center at a roundtable about antibiotic resistance in New York, organised by the Society of Infectious Diseases of America, the Society for Healthcare Epidemiology of America, and the Society of Infectious Disease Pharmacists (April 2003)

<sup>2</sup> statement by the National Antimicrobial Resistance Monitoring System (NARMS) in the USA

<sup>3</sup> <http://www.ghchealth.com/glaxo-chief-our-drugs-do-not-work-on-most-patients.html>

<sup>4</sup> WHO definition of adverse drug reaction: any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy. This definition excludes therapeutic failures, intentional and accidental poisoning (i.e. overdose), and drug abuse. Also this does not include adverse drug events due to errors in drug administration or non-compliance.

were caused by the inherent toxicity of prescription drugs that are properly prescribed and administered. This study was criticised for various reasons, but it certainly made the medical world aware of a serious problem. In their 2002 report *Safety of medicines* the WHO clearly states that ‘medicines morbidity and mortality is one of the major health problems’.

A recent, large prospective study by Pirmohamed (2004) in the UK confirmed the Lazarou study as to the incidence of fatal adverse drug reactions as a cause of admission to hospital. Ebbesen (2001) and Buajordet (2001), who based their findings on autopsy findings and/or pre-mortem and post-mortem drug analysis data, showed that drug-related side effects may contribute to 18% of all hospital deaths. In half of the cases medication errors were causative and therefore these could potentially all be avoided. Even more alarmingly, it appeared that treating physicians classified only 6% of drug-induced fatalities as such, which means that 94% of the fatal adverse drug events<sup>5</sup> (ADEs) went unnoticed. Schnurrer (2003), in a recent review on the frequency of ADRs and ADEs, asserts that the risk of drug therapy is grossly underestimated and estimates that 57,000 patients in internal medicine wards in Germany die from fatal ADEs each year.

Suitable services to treat ADRs impose a high financial burden on healthcare due to the hospital care of patients with drug related problems. Some countries spend up to 15-20% of their hospital budget dealing with drug complications (White, 1999). The estimated national costs of hospital related adverse events in the USA are \$37.6 billion and of preventable adverse effects to be \$17 billion per annum (Kohn, 2001). Drug-related morbidity and mortality in the ambulatory setting is estimated as high as \$76.6 billion per annum (Kohn, 2001).

Gandhi (2000) showed that almost 1 out of 5 patients who take prescription drugs experience a treatment-related complication. In this study on 2,248 randomly chosen patients 18 percent of them reported complications from treatment, but only one-sixth of these adverse reactions were reported in the medical chart. Approximately 50% of patients who experienced an adverse reaction sought medical attention as a consequence of it, and 5% of them were hospitalized. These figures show that drug-related complications occur significantly more often than reported in patients' medical charts, leading to extensive utilization of the healthcare resources and patients' dissatisfaction with quality of care. This study is particularly important because it presents rates of adverse drug reactions in outpatient settings, where most of the medications are given, and because it reveals how the vast majority of adverse reactions are unreported.

Furthermore, it seems that the person who suffers from an iatrogenic disease may also develop a second iatrogenic disease as a result of medical treatment for the original iatrogenic disease. It is estimated that in the USA for every dollar spent on ambulatory medications, another dollar is spent to treat new health problems caused by the medication (Kohn, 2001). In view of these facts it is not surprising that the incidence of iatrogenic diseases is increasing alarmingly, so much so that it has been described as ‘epidemic’.

### 1.6. Medication errors

Although medical errors are not inherent to the medical model or any particular therapy, the toxicity of the drugs makes these errors to have serious and sometimes fatal effects. In a

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<sup>5</sup> WHO definition of adverse drug events: any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment.

review of US death certificates between 1983 and 1993, it was found that 7,391 people died in 1993 from medication errors (accidental poisoning by drugs that resulted from acknowledged errors by patients or medical personnel), compared with 2,876 people in 1983, representing a 2.57-fold increase (Phillips, 1998). Outpatient deaths due to medication errors rose 8.48-fold during the 10-year period, compared with a 2.37-fold increase in inpatient deaths. These data, already alarming, become even more preoccupying when considering that many errors go undocumented and unreported (Kohn, 2000).

### 1.7. Health care being impersonal and too technologically oriented

Patients increasingly feel that medicine has become too impersonal and technological and that doctors spend more time looking at their lab reports and ultrasound scans, rather than with them. Patients may undergo all kinds of medical investigations just to find a demonstrable organic disease/abnormality that is held responsible for the patient's complaints. Clearly, medical technology distances the relationship between patient and physician resulting in a depersonalizing treatment of the patient as an object. The use of medical technology also has a dehumanizing effect on physicians who cannot rely on their clinical skills the way they have traditionally.

### 1.8. Conclusion

As a conclusion, Europe is confronted with ever increasing health care expenditure, an increasing prevalence of chronic diseases and failure of effectively managing them, a huge burden of adverse side effects and mortality due to the toxicity of prescription drugs, and growing resistance to antibiotics. In addition, healthcare is seen as impersonal and too technologically oriented.

## **2. Biomedicine as the predominant medical model**

Since the challenges mentioned in the previous chapter may be inherent to the medical model on which the current European healthcare system is based, this chapter examines this model more in depth.

The predominant medical model in Europe (and the rest of the Western world) is biomedicine, also called school medicine, modern medicine or technological medicine. Biomedicine understands itself as a medicine based on the principles of natural science, such as biology, biochemistry, and biophysics. In other words, its insights and therapies are understood to be universal and thus to be transferred and practiced worldwide (Kalitzkus, 2004). Biomedicine is increasingly understood as one of many medicines, i.e. culturally and historically specific and far from universal.

### 2.1. Basic tenets of biomedicine

According to anthropologists Lock and Gordon (1988), Kleinman (1995) and Hahn (1995), biomedicine has the following tenets:

- Illness and disease are conceived of as 'natural' phenomena.

While the terms 'illness' and 'disease' are often used interchangeably, it is useful to differentiate between them. Illness may be defined in terms of the patient's experience of dysfunction (pains in their myriad combinations and dimensions, discomfort, numbness, nausea, dizziness, panic, fatigue); it is the

opposite of wellness, an impaired sense of wellbeing. Disease implies the presence of objectively identifiable abnormalities in physiological or biochemical pathology of body function or structure (temperature, sedimentation rate, enlarged liver, deviating CAT or MRI scans, bone mass loss, circulating antibodies etc.). Disease can be independent of the subjective experience of the person and even be asymptomatic. The distinction between disease pathology and illness experience is valuable because it helps us remember that while health and illness are polarities, health and disease need not necessarily be so. In general, it is the illness that drives people to the doctor and it is the illness people want to lose.

There is talk in biomedicine of ‘natural course’ and ‘natural or spontaneous remission’ i.e. relief from disease without medical intervention; it is implied that what is not treated medically is natural or even spontaneous (without cause), and it is further suggested that the ‘natural’ and the ‘medical’ are complementary and mutually exclusive domains.

- Illness can be categorized into specific diseases characterised by identifiable organic pathology and is considered to be explained when this pathology has been diagnosed.
- Disease in biomedical terms is considered to have an identity separate from their specific hosts and conceptualised as a defect of biological and chemical processes of the body that need to be ‘repaired’ and restored to the biomedically defined norms. These biomedical norms for the human body are most obvious in all the tables of standards for various biological parameters such as weight, blood pressure, cholesterol, blood sugar and so on. It is assumed that the presence or absence of disease can be empirically defined and determined by laboratory or other biological or physical tests.
- Understanding and knowledge of the molecular basis of the body will eventually solve all medical problems.
- Healing is a matter of applying the best available technical methods to diagnose and treat the medical condition of patients. The healing process is regarded as a physical one in which bodily malfunction is altered by the medical introduction of physical materials or the surgical modification of bodily arrangements. Subjectivity on the part of the physician (and of the patients) is regarded as an obstacle to effective therapeutic practice.
- Patients are passive recipients of the intervention, since patients differ only in complexity from disabled machines requiring repair.
- Biomedical practice and research is objective, neutral and scientific.

### *2.1.1. Elimination of symptoms, no search for optimum health*

From the biomedical perspective the importance of symptoms is commonly confined to their ability to indicate the presence of, or confirm the diagnosis of, a predefined disease, which itself is just a symptom of a more fundamental metabolic disturbance or illness. Since the goal of biomedicine is to remove symptoms of disease rather than attain a condition of optimum health, the elimination of symptoms becomes an end in itself rather than a means of identifying and correcting the underlying cause of disease (Millenson, 1995). In this setting, there is little incentive to search for causes.

According to Woodhouse (1997) the concept of health in the biomedical model functions essentially as a default value. That is to say, health is what is ‘left over’ when a person is free of all disease and obviously predisposing factors to disease. Physicians are trained, first and foremost, to diagnose and treat disease and only secondarily to promote health in all but the most rudimentary arenas of prevention, such as smoking and prenatal care. An important reason why physicians do not promote health as readily as they attack disease is that the biomedical model does not offer a robust concept of health to begin with.

Biomedicine does not seek to attain a condition of optimum health, but rather aims to

eliminate symptoms of specific diseases. This is achieved predominantly by the use of symptom suppressing drugs and by the surgical removal or replacement of diseased tissues or organs. Biomedicine is intrinsically *interventionist*, that is, the medical practitioner prefers to actively intervene in the patient's illness in an attempt to be seen as having *fixed* the problem. Biomedicine battles with the forces of disease conceived of invaders from without, alien bacteria, viruses and other microbes which are bent on our destruction. The preoccupation with destruction of microbes has displaced any interest in optimising the natural immunity of the patient. Variations in natural immunity, even when it comes to serious diseases, remain unexplained and unexploited.

Biomedical drugs are intended to act *against* diseases, which is also shown by their names: anti-biotics, anti-viral drugs, anti-inflammatory drugs, anti-retroviral drugs, anti-hypertensive drugs, anti-cancer drugs, anti-HIV-1 drugs, anti-thrombosis drugs, anti-rejection drugs, anti-arrhythmic drugs. They *block* some identified ongoing patho-physiological process e.g. block tumor angiogenesis, block monoclonal antibodies, block interleukin-5, block Very Late Antigen-4, block histamine, block adrenergic receptors, block DNA replication, block prostaglandin synthesis, block Tumor Necrosis Factor- $\alpha$ , block mitochondrial permeability transition, block Angiotensin Converting Enzyme, block B-adrenergic receptors, etc.

### *2.1.2. Technical approach of patients as passive recipients of treatment*

Technological means of diagnosis and intervention are greatly preferred over interpersonal and social means. Non-technological activities, such as talking with patients, may not be considered part of treatment at all. Millenson (1995): 'The strictly medical interview consists of a search for signs and symptoms in order to reach a decisive diagnosis by exclusion. This kind of objective medical interview, however valuable it may be for eliciting the facts of physical disease, will not do for grasping the full nature of illness with its multi-faceted, biopsychosocial dimensions. Aside from the power dynamics which put the person-patient in the dependent, dehumanizing role of an object that complies or otherwise, such an interview inhibits the development of an authentic patient/physician relationship'.

The biomedical view on man, health and illness focuses primarily on the biophysiological aspects. The development of biomedicine resulted in a loss of subjectivity and meaning in illness. The focus shifted from the subjective description of illnesses by the suffering individual to the search for objective medical facts. Through this transition, the patient's body was transformed into a passive object for medical inquiry. Many modern physicians seem to order the value of medical evidence in a hierarchy: facts obtained through complex scientific procedures they regard as more accurate and germane to diagnosis than facts they detect with their senses, which, in turn, they value more than facts disclosed by the patient's statement (Reiser, 1978).

### *2.1.3. No answer to functional somatic symptoms or subclinical disorders*

Since biomedicine must wait until a predefined disease becomes established before diagnosis and treatment is possible, the biomedical practitioner has hardly any tool in managing functional somatic symptoms or sub-clinical disorders. In functional somatic symptoms there is an abnormality in the physical functioning of the body, but these symptoms are not caused by disease detectable by physical examination or routine laboratory investigations, although specific physiological changes can be detected in some of these symptoms by special

techniques (Kellner, 1985). It is in this area, the area of prevention and treatment of subclinical disease where orthodox medicine has been inept<sup>6</sup>.

Functional somatic symptoms are of clinical importance, because as many as one in five new consultations in primary care are for somatic complaints for which no specific cause can be found (Bridges, 1985). Whilst many of these complaints are transient, a sizeable proportion are persistent and associated with great suffering, distress, disability and substantial societal costs (Kroenke, 1994; Barsky, 1999). Medically unexplained symptoms are common across general/internal medicine and represent the most common diagnosis in some specialities (Carson, 2000; Nimnuan, 2001; Reid, 2001).

The ineffectiveness of biomedicine in these patients is presumably because negative investigations, and hence physicians, tell patients what is *not* wrong with them, rather than what is. The patient who suffers somatic symptoms for which the physician can find no demonstrable organic disease is often told that the illness is all in his or her mind. Thus if medical investigations are negative, the problem is not ‘physical’, and if it is not physical, it must be ‘mental’. This approach conceives of functional somatic symptoms as psychiatric disorders – also termed as ‘somatisation disorder’ – produced by mental mechanisms (Watkins, 1997). Functional somatic symptoms are typically viewed from one of two distinct and polar perspectives; one is mentalist or psychiatric, the other physicalist or biomedical. The pervasive, if not always explicit assumption, that mind and body are separate (mind-body dualism) leads to illness being regarded as *either* ‘physical’ *or* ‘mental’ in nature (Mayou, 1995). This dichotomization is further complicated by moralistic prejudices which assume that illnesses classified as mental imply a degree of personal weakness or inferiority on the part of the sufferer (Kirmayer, 1988; Stone, 2002). In fact, functional somatic symptoms and syndromes cannot be adequately understood either as simple expressions of physical pathology, or in terms of a traditional psychiatric framework. Instead, it can only be achieved by introducing a holistic framework (see chapter 3).

## 2.2. Prevention within the biomedical model

Biomedical practice values curative interventions above preventive ones, although the curative approach is often not the most effective or efficient available means for promoting patients’ health. In general, physicians are paid far more for technological procedures than for counselling their patients about lifestyle or other predisposing factors. Since prevention is cheaper than cure, which has been amply demonstrated through cost-benefit analyses of prevention programmes, modern medicine has started to investigate this area. Modern prevention within the biomedical model, as anthropologist Rabinow (1995), cited by Kalitzkus (2004), points out, is especially concerned with the identification of risk factors. Risk is understood as a composite of impersonal ‘factors’ increasing the possibility of an illness. These factors are pinned down in relation to statistically derived norms.

### *2.2.1 Life-style related risk factors*

According to the recent CINDI (Countrywide Non-communicable Disease Intervention) report it is well documented that major chronic diseases share common preventable lifestyle-

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<sup>6</sup> Somatic symptoms are common in the general population. The lifetime prevalence of a number of somatic symptoms as elicited in a US population survey shows: joint pains (37%), back pain (32%), headache (25%), fatigue (25%), chest pain (25%), arm and leg pain (24%), abdominal pain (24%) and dizziness (23%). One-third of all the symptoms reported were unexplained by disease (Kroenke, 1989).

related risk factors such as tobacco, unhealthy diet, alcohol abuse and reduced physical activity. In addition, risk factors for chronic diseases can be linked directly to social, economic and environmental determinants of health. Psychosocial stress is generally regarded as a contributing factor in a number of conditions including coronary heart disease and hypertension.

### *2.2.2 Chronic disease policy*

At the European Union level comprehensive action has been taken to counter health damage caused by tobacco products, alcohol and other drugs. Initiatives on nutrition and physical activity included actions to improve available information and to disseminate best practices. A network of expert institutes was established in 2003 to support measures to promote varied and healthy diets, to combat obesity and encourage physical activity. A large proportion of European Member States, however, still does not have a chronic disease policy. Their health systems continue to respond to emerging problems of chronic diseases in a rather fragmented way, their budgets to cope with chronic diseases are inadequate, and chronic diseases arouse very little interest in the mass media and limited action in society (CINDI report).

The irrelevant nature of the biomedical model when it comes to disease prevention is amply demonstrated by the fact that currently accepted recommendations for disease prevention usually involve the adoption of traditional holistic advice. For instance, suggestions that diseases like heart disease or cancer may be prevented by lifestyle factors such as diet and nutrition merely reflect an acceptance of traditional holistic views (see next section on the holistic model).

### 2.3. Strengths and shortcomings of the biomedical model

Biomedicine has earned an impressive reputation, when it comes to emergency medicine, trauma, the treatment of life threatening conditions or conditions with irreversible tissue damage, and, in addition, the possibilities of medical technology — whether the use of miniature robots for surgery, genetic therapies, growing replacement organs and tissues. The typical patient/physician relationship in biomedicine, with a relatively inert patient's role, fits well to biomedicine's interventionist, symptom based approach and the preferred use of toxic or invasive treatments and diagnostic procedures.

On the other hand, it has been increasingly acknowledged that biomedicine is failing in three major areas. The first of these is safety, because of the increasing incidence of iatrogenic diseases and drug mortality. Secondly, the biomedical model is far less suitable, or even inadequate, in chronic relapsing illnesses where multiple causes interplay or in functional and sub-clinical illnesses where no anatomical pathology has evolved (as yet), and the collaboration of the patient is of paramount importance. Thirdly, the high tech interventionist nature of biomedicine has little or no role to play in disease prevention.

Patients are becoming more and more worried about issues such as the adverse effects and toxicity of many conventional drugs – in fact a major cause of death and hospitalization –, the growing resistance to antibiotics, and the inability of conventional medicine to cure chronic diseases. Increasing numbers of patients, although not giving up biomedicine (Astin, 1998a), look for less-toxic alternatives, especially for chronic illness. Many mainstream general practitioners share their patients' concerns about biomedicine, and are either referring to or

practising some of the more prominent and well-known forms of complementary and alternative medicine (Astin, 1998b; White, 1997) (see section 3.8).

### **3. Holistic or biopsychosocial model**

Attempts to counterbalance the shortcomings of the biomedical approach concentrate on putting the patient back into centre view and looking for other forms of concepts on health and illness (Kalitzkus, 2004). The term ‘holistic’ in healthcare implies that any therapy deals with illness as a dysfunction of the mind and body as an integrated whole. It was already in 1977 that Engel, in his article in the well-known journal *Science*, argued for the need for a new medical model and coined the term biopsychosocial model.

#### 3.1. Human beings as complex living systems

Within the holistic model the individual is seen as a unified, dynamic, non-linear, complex living system, integrated within a specific physical and social environment. A living system that is composed of subsystems that are in some ways machinelike, but also part of higher order systems that cannot be explained by mechanical principles. These higher-level systems make individuals psychosocial beings. Individuals cannot be completely understood by the law of physics, chemistry, molecular biology or anatomy and physiology, even though these laws are operating within them. They are living systems that are self-healing, self-renewing, homeostatic and adaptive.

The holistic model describes interactions between psychosocial and biological factors in the etiology and progression of illness and disease. How an individual interprets and responds to the environment determines responses to stress, influences health behaviour, contributes to the neuro-endocrine and immune response, and may ultimately affect health outcomes. The actual manifestation of disease is always multi-causal and depends on the conjunction of precipitating psychosocial and pathogenic factors, along with constitutional susceptibilities in particular organ systems (Millenson, 1995).

Resistance to infections, for instance, varies enormously between medically normal people. Most people would know of someone who rarely succumbs to any infection. Such a person can go for 10 or 20 years without even catching a cold even though his/her associates or friends may repeatedly catch infections. And even in a flu epidemic, most people remain unaffected.

An interesting example is that of Pettenkofer. The German chemist Pettenkofer reduced Munich's death rate due to typhoid from 72 per 1,000,000 in 1880 to 14 in 1898 by increasing the supply of fresh water and by diluting the city sewage. When Robert Koch, German scientist and founder of modern medical bacteriology, isolated the cholera bacillus and confirmed it as the cause of cholera, Pettenkofer disputed Koch's finding and said that diseases are caused not by bacteria but by poor hygiene. To prove his point, Pettenkofer obtained from Koch a culture from a fatal case of cholera and swallowed a large amount of the culture. Even though he consumed massive numbers of organisms in comparison to accidental infection and on all occasions the stools were found swarming with the cholera bacilli, he only had a minor attack of diarrhoea.

A well-known historical argument between Louis Pasteur and Claude Bernard was about whether the most important factor in communicable disease was the terrain (the human body) or the germ. Bernard put forth the concept that the body always works to maintain a delicate balance in the chemistry and functioning of its many parts. When the balance is disturbed, illness and death can result. Bernard said, ‘Diseases hover constantly above us, their seeds are blown by the wind, but they take root only when the terrain is ready to receive them.’ Pasteur's last words were reported to be, ‘Bernard was right. The germ is

little, the terrain all.’ In other words, micro-organisms are capable of infecting a person when it gets, as it were, a suitable nidus for propagation.

In other words, micro-organisms are a necessary but certainly not a sufficient cause for communicable disease. When strong, the immune system keeps people healthy in spite of their constant exposure to germs that permeate everyone’s environment. Another example is the susceptibility to cancer. It is well known that most lung cancers are smoking related. Still, most smokers will not develop lung cancer. Biomedicine is focused on the question: ‘Why do people contract various diseases, and what can we do to reduce their occurrence?’ Although certainly concerned about these questions, the holistic physician additionally asks: ‘Why do some people remain healthy throughout their lives, despite being exposed to the same factors as those who become ill?’.

According to Millenson (1995), the individual is influenced by three external kinds of disease-inducing agents, i.e. environmental hazards, infectious agents and potential stressors. Typical examples of each of the three categories of causal disease-predisposing events are:

- Environmental hazards: radiation, pollution, injuries, allergens, drugs, cosmetics, noxious fumes;
- Infectious agents: viruses, bacteria, fungi, protozoa, parasites.
- Potential stressors: loss of loved one, loss of job, time pressure in work, financial crisis, interpersonal frustrations, boring work, executive responsibilities, childhood emotional deprivation/traumas, examinations, unemployment, intractable family problems, rejection, unresolved intra-personality conflicts, etc.

It is to be noted that the existence of any one of the above-mentioned agents does not in itself produce disease. These causal agents might be necessary, but not sufficient causes. In fact, **all** disease is multi-factorial in causation, and whether any particular illness is organic or psychosocial is rarely black or white. Whether or not an organic malfunction can be detected is largely a function of the resolving power of our current laboratory tests and the sophistication of our present concepts of disease process.

A certain genetic make-up may predispose to a particular disease but cannot predict with certainty the onset, progression or severity of disease. Genetic disposition is often lying dormant but can be triggered by events. Disease develops as a consequence of interactions between the initial conditions, coded in the genotype, and exposures to environmental hazards, infectious agents and potential stressors. Genes are not static however, but far more malleable than previously imagined. In fact, people’s mental state can increase the number of genetic mutations and impair the body’s ability to repair them (Kiecolt-Glaser, 2002).

### 3.2. Concept of disease according to the holistic model

Woodhouse (1997) described the concept of disease according to the holistic model, as follows: “In the holistic model disease is defined as a breakdown, block, or imbalance somewhere in the systems, subsystems, and meta-systems that comprise an otherwise healthy person, including the person’s relationship with physical and social environments. Symptoms are not the disease, but merely evidence that such a breakdown has occurred. Holism seeks to push the causal chain of factors leading to this imbalance into territory typically left uncharted, and sometimes unimagined, in the biomedical model. It does not deny the efficacy of the necessary and/or sufficient physical conditions stressed by the biomedical model, e.g. HIV is necessary but not sufficient for AIDS. Rather, it seeks to identify and treat a wide spectrum of predisposing factors that individually may seem irrelevant to the patient’s

symptoms, but that collectively can lead to disease. Holism does not reject the biomedical concept of disease, nor does it attempt to replace it with his/her own. Rather, it seeks to include all that expand this concept to include a wide spectrum of predisposing factors that the average medical doctor typically (although not necessarily) has neither the time, the interest, nor the training to explore. In general, the biomedical model draws narrower boundaries, whereas the holistic model draws wider boundaries. This is why the holistically oriented physician has an information form five times larger than the traditional provider's for an initial consultation."

Woodhouse (1997) continues: "According to the holistic model, most people are more or less in a continuing state of moderate ('sub-clinical') disease, even though they may not be manifesting symptoms of any particular disease. They are in these states of disease to the degree they are not in the state of optimum health. We typically only apply the label of 'disease' when we are so far removed from optimum health that specific symptoms are encountered, but if our immune systems are working only moderately well, then we are moderately diseased, even if there are no symptoms of specific disease. The manifestation of the symptoms is simply the lowest point on the scale at which one is most diseased, i.e. the farthest from optimum health. Once they manifest, the holist insists that the symptoms, plus the inner physical causes, and everything that contributed to the patient's inability to resist disease, are all part of the 'disease'."

According to the holistic model, disease is the default negative value resulting from a failure to maintain optimum health (Woodhouse, 1997) and health is not merely the absence of disease or infirmity, but the ability of a system, e.g. cell, organism, family, society to respond adaptively to a wide range of environmental challenges, e.g. physical, chemical, infectious, psychological, etc. (Brody, 1979). Disease is a failure of adaptive response, resulting in disruption of the overall equilibrium of the system. Consequently, the way to treat disease is not so much to attack the symptoms or the immediate underlying pathology as it is to restore the patient to a state of overall health (Woodhouse, 1997).

Most diseases may be 'silent' in the body for a considerable period of time before they actually become diagnosable. This period of 'silence' of course, represents the sub-clinical stage of disease, which has been almost abandoned by biomedicine. This is the stage of illness between the condition of optimum health and the emergence of definite signs of clinical disease, a stage which is impossible to diagnose when the state of optimum health is neither accepted nor understood. The importance of recognising the early stages of illness, of course, stems from the fact that it is at this point that the condition is most easily reversed.

### 3.3. Diagnosis of disease within the holistic model

Woodhouse (1997): "Contrasting approaches to the diagnosis of disease logically follow from the diverging concepts of health and disease. The biomedical model offers a diagnosis based on manifest symptoms plus the underlying proximate physical pathology. The holistic model is entirely consistent with, and encompassing of, such diagnoses, but then goes in search of additional components that directly and indirectly contribute to the onset of a specific disease. How one diagnoses a disease is directly related to how one conceives the range of treatment modalities; to treat the disease is to treat what one has defined as the disease. If cancer is merely its overt symptoms and pathology, and nothing more, then that is what one must treat. On the other hand, if cancer is its symptoms and its pathology, plus a spectrum of other

clinical and sub-clinical predisposing factors, then one's treatment options are magnified accordingly.

There is another reason why this distinction between restricted and expanded diagnoses of cancer is critical. If one acts only on the restricted definition of the disease, and fails to address the broader range of contributing factors, then apparent success in treating the symptoms leading to a remission will leave open the probability of recurrence several years later. In this event, the original treatment will be described as only 'partly successful' – meaning that it failed to do what everyone hoped it would do. One of the reasons it failed, from a holistic perspective, is that the diagnosis of cancer was so narrowly proscribed in the first place. The surgeon who 'gets it all' is understandably pleased. The holistic practitioner who sees the patient returning to a life of despair is not as optimistic about remission.

It should be emphasised that the holistic practitioner is not drawing attention merely to the obvious predisposing factors, such as smoking in the case of lung cancer or fat and cholesterol in the case of heart disease. Dozens of other factors already alluded to both may predispose one towards cancer and simultaneously detract from optimum health. Many may seem to have nothing to do with cancer per se, but instead weaken the immune system's ability to resist cancer, as well as other diseases. The holist is more concerned with the multiple factors that contribute to overall health, but taken individually are often neither necessary nor sufficient for the occurrence of specific diseases."

The strictly medical interview within the biomedical model consists of a search for signs and symptoms in order to reach a definitive diagnosis by exclusion. This kind of objective medical interview, however valuable it may be for eliciting the facts of physical disease, will not do for grasping the full nature of illness with its multi-faceted, holistic dimensions. Aside from the power dynamics, which put the patient in the dependent, dehumanizing role of an object, such an interview inhibits the development of an authentic patient/physician relationship, the very ingredient necessary for a holistic diagnosis. It is only in the context of relationship that the illness story can emerge in such a way that the practitioner can begin to grasp its nature and therefore propose a rational treatment plan.

Watkins (1997): "The adoption of a biopsychosocial approach changes the way a physician takes a history, examines a patient and ultimately manages their problem. It also allows for more creativity and scope to respond to the human dilemma of illness and minimizes the tendency to see individuals as biological subjects to be fitted into treatment protocols. Creative solutions to individual dilemmas need to be considered, and these may not necessarily come from traditional sources. Complementary and alternative approaches may have much to offer, particularly in the absence of effective conventional approaches. Physicians should not attempt to take responsibility for all the patient's problems and attempt to 'solve' them. Rather, physicians should help patients to understand their illness, provide guidance and advice, and recommend intervention where appropriate. It is important to identify what resources are available to the patients for recovery, and what treatments can facilitate the recovery and restoration of function."

### 3.4. Treatment within the holistic model

Woodhouse (1997): "The treatment of preference for cancer under the biomedical model is some combination of surgery, radiation and/or chemotherapy, plus eradicating any lifestyle factors that directly contribute to the cancer. A support group may be recommended, but mainly to help one deal with the emotional challenge brought on by the disease (e.g. fear of death). The average oncologist does not believe that presence or absence of love in a patient's

life, for example, has anything to do either with the causes or the cures for cancer. Thus, he focuses on treating the specific manifestations of cancer, usually tumorous growth, with drugs and surgery.

To use the battle metaphor, the holistically oriented physician, although not necessarily rejecting the aforementioned treatments (depending on the stage of the disease), ‘goes after’ a whole different segment of the health-to-disease spectrum. He may prescribe homeopathic medicines (to strengthen the constitution of the patient), nutritional analysis and support, and psychotherapy (not merely to help the patient ‘deal’ with the illness, but to undertake certain core emotional release work around, say, the lack of forgiveness and guilt associated with childhood trauma, which has subsequently restricted the ability to give and receive love).

None of these treatment modalities directly fight cancer *per se*. All indirectly fight it by supporting other systems in the background, the optimum function of which will support the fight with or without the use of traditional surgery and chemotherapy. Surgery may well be necessary as an immediate counter measure, but in the overall long-term view of matters, the holist proceeds on the assumption that it is best to restore all of the patients’ own natural systems for fighting disease to optimum efficiency. This is why, from the traditional perspective, the holist’s treatment modalities appear to have nothing to do with fighting cancer *per se*. They are less locally aimed at the tangible manifestations of cancer, but instead are non-locally ‘spread out’ to other systems of both higher and lower order complexity throughout the patient’s body and brain/mind. The more non-locally spread out they are, the less individually necessary and/or sufficient they will be for particular diseases, although collectively they predispose one towards diseases in general. Thus understood, biomedicine and alternative treatment methods are not merely different procedures aimed at the same target. They are different procedures aimed at different targets.”

In the holistic model healing is considered as a process in which social interaction and societal organisation play a prominent role, along with medical procedures. The social and psychodynamic interrelations of physicians and patients are recognised as critical elements in the healing process (Hahn, 1995). As Saunders (1954) has written, “the social relationship is not something apart from medical practice which, like the icing on the cake, can be included or left out at the discretion of the practitioner. It is rather an integral and necessary part of medical practice, without which there is no practice”.

The holistic model of health and disease shifts a greater responsibility not only for health maintenance, but also for treatment of disease, from the provider to the patient. It gets the patient more actively involved in managing his or her health and disease. The concept of self-care requires a daily conscious focus on one’s physical, mental, and emotional state and the ability to take corrective action whenever imbalance is sensed. According to Rosenman (1997), it appears prudent to pay increased attention to the individual who possesses a risk factor, and not the risk factor *per se*.

### 3.5. Complexity science and systems theory

Non-linear thinking has grown among physiologists and physicians over the past century, and non-linear system theories are beginning to be applied to assist in interpreting, explaining, and predicting biological phenomena. Complexity science is the study of complex adaptive systems – the patterns of relationships within them, how they are sustained, how they self-organize and how outcomes emerge. This emerging science is highly interdisciplinary including biologists, anthropologists, physicians, economists, sociologists, management theorists and many others in a quest to answer some fundamental questions about living,

adaptable, changeable systems. Articles on complexity science have also started to be published in mainstream medical journals (Goldberger, 1998; Wilson, 2001; Bell, 2002).

Complexity science has contributed to the development of a new, integrated concept of disease and therapeutics (Coffrey, 1998). Human beings can be viewed as composed of and operating within multiple interacting and self-adjusting systems, including biochemical, cellular, physiological, psychological, and social systems (Wilson, 2001). Illness arises from dynamic interaction between these systems, not from failure of a single component. Health can only be maintained – or re-established – through a holistic approach that accepts unpredictability and builds on subtle emergent forces within the overall system. Complexity science suggests an alternative model that illness (and health) result from complex, dynamic, and unique interactions between different components of the overall system. For all these reasons neither illness nor human behaviour is predictable and neither can safely be ‘modelled’ in a simple cause and effect system. The human body is not a machine and its malfunctioning cannot be adequately analysed by breaking the system down into its component parts and considering each in isolation.

Few, if any human illnesses can be said to have a single ‘cause’ or ‘cure’. On the contrary, they result from complex, dynamic, and unique interactions between different components of the overall system (Wilson, 2001). Psychological stressors, infectious agents, injury etc. are viewed as destabilizing factors, whereupon internal system agents act or are ready to act to maintain constancy or homeostasis. These agents are connected and continuously evolving, recycling and adapting within each system. Health human systems are characterized by variability and elasticity, whereas regularity, or fixed response, indicates illness and pathology.

Much of biomedicine and biomedical research techniques have not kept up with advances in other scientific fields. Conventional scientific medicine is still based on a Newtonian model of science, while physics itself has become much more complex. When new findings of physics and the human sciences become integrated into medicine, many of the claims of holistic medicine will not appear so far-fetched.

### 3.6. Psychoneuroimmunology

Until very recently, a person’s emotional health and wellbeing was considered essentially irrelevant to his or her physical health and wellbeing, according to the biomedical model. The emergence of psychoneuro-immunology, as a rapidly emerging field of research in its own right, has causally implicated unhealthy emotions and attitudes in a variety of physical diseases. There is now a substantial amount of evidence from research into the mind (psychology), the brain (neurology) and the body’s natural defences (immunology) to suggest that the mind and body communicate with each other in a bidirectional flow of hormones, neuropeptides and cytokines (Watkins, 1997). Virtually all of the body’s defence systems are under the control of the central nervous system (CNS), which implies that every idea, thought and belief has a neurochemical consequence, and neuropeptides flow from the CNS, impinging on specific receptors on virtually all leukocytes, regulating their function (Watkins, 1997)

Immune dysregulation has been shown to be one core mechanism for a spectrum of conditions associated with ageing, including cardiovascular disease, osteoporosis, arthritis, Type 2 diabetes, certain cancers, infectious disease, Alzheimer’s disease, wound healing,

periodontal disease and frailty and functional decline; production of proinflammatory cytokines that influence these and other conditions can be stimulated directly by negative emotions and stressful experiences, and indirectly by prolonged infection (Kiecolt-Glaser, 2002).

There is substantial evidence from both healthy populations as well as individuals with cancer linking psychological stress with immune down-regulation. This discussion highlights natural killer (NK) cells, because of the role that they may play in malignant disease. In addition, distress or depression is also associated with two important processes for carcinogenesis: poorer repair of damaged DNA, and alterations in apoptosis (programmed cell death) (Kiecolt-Glaser, 2002). Several studies suggest that psychological or behavioural factors may influence the incidence or progression of cancer through psychosocial influences on immune function and other physiological pathways. Resources such as close personal relationships that diminish negative emotions enhance health in part through their positive impact on immune and endocrine regulation. There is increasing evidence that life stress may constitute an independent risk factor for progression and/or persistence of squamous intraepithelial lesions in HIV-infected women, which may lead to cervical intraepithelial neoplasia and cancer (Pereira, 2003).

In a broad meta-analysis Zorrilla (2001) showed that both major depression and naturally occurring stressors have the following physical effects: leukocytosis, increased CD4/CD8 ratios (the ratio of CD4-helper cells to CD8-suppressor cells), reduced proliferative response to mitogen, and reduced natural killer cell cytotoxicity.

It is well established that psychological factors, such as business failure, major intrafamily conflict, job loss, death of spouse etc. can act as risk factors in myocardial infarction (Rosengren, 2004). In fact, the size of the effect of psychological factors has been shown to be somewhat less than for smoking but comparable with hypertension and abdominal obesity (Yusuf, 2004). Bunker (2003) showed that significant depression will increase the risk for coronary disease by five times. In experimental studies, worsened coronary atherosclerosis and endothelial dysfunction happen in response to social disruption. Several studies have shown links between psychosocial variables and vascular function, inflammation, increased blood clotting, and decreased fibrinolysis (Rosengren, 2004).

There is some evidence that cognitive behavioural stress management intervention is associated with alterations in mood, neuro-endocrine functioning and immunologic status that may have health implications for HIV infection (Antoni, 2003). Other studies indicate that psychotherapeutic intervention can augment natural killer cell activity and lymphokine-activated killer cell activity in patients with malignant melanoma and with locally advanced, non-metastatic breast cancer respectively (Greer, 1999).

Stress and personality can be factors in the etiology of a disease, after which the greatest stress is the dysfunction created by the illness itself. Some illnesses may actually be operantly reinforced. Others may have begun with a trauma or an infection, but then be exacerbated or maintained by personality factors that take over and perpetuate the illness long after the precipitating factor is gone. In other cases the initial factor might well have been stress, but the illness long outlives the initial predisposing stress condition due to new factors arising out of the consequences of being ill. Then too, the temporal relation between stress and illness is not necessarily a simple one. People sometimes get ill after the stressor has passed and gone. These are just a few illustrations of the many ways that emotional parameters can enter into

the pathogenesis of a disease; in any particular case these psychological aspects could be combined, permuted or interactive (Millenson, 1995).

Holistic practitioners consider psychoneuroimmunology a welcome development, but carry matters much further. According to the holistic model, all illness has underlying emotional components that predispose one toward specific diseases. Whether disease results, of course, depends in part on the degree of emotional unhealthy and many other factors of a physical sort, such as environmental toxins or genetic predispositions.

### 3.7. Nutrition

The last 50 years have seen a vast accumulation of scientific research on nutrition in all areas of health and disease. The 2003 WHO report on ‘Diet, nutrition and the prevention of chronic diseases’ underlines nutrition as a major modifiable determinant of chronic disease, with scientific evidence increasingly supporting the view that alterations in diet have strong effects, both positive and negative, on health throughout life. As the report says, ‘Most importantly, dietary adjustments may not only influence present health, but may determine whether or not an individual will develop such diseases as cancer, cardiovascular disease and diabetes much later in life. [...] Although more basic research may be needed on some aspects of the mechanisms that link diet to health, the currently available scientific evidence provides a sufficiently strong and plausible basis to justify taking action now. Beyond the appropriate medical treatment for those already affected, the public health approach of primary prevention is considered to be the most cost-effective, affordable and sustainable course of action to cope with the chronic disease epidemic worldwide. The adoption of a common risk-factor approach to chronic disease prevention is a major development in the thinking behind an integrated health policy’. According to Eurodiet, a pan-European project that started in 1998, nutritional factors and inactive lifestyles are implicated in 30-40% of cancers and at least one third of premature deaths from cardio-vascular diseases in Europe (Eurodiet, 2000).

Apart from prevention, there is considerable published and ongoing research investigating nutrition as a treatment. There are thousands of papers on research carried out in prestigious academic and government-funded laboratories, published in respected, peer-reviewed medical and scientific journals. The research encompasses a wide expanse of methodologies, ranging from determining the optimal dosage of single nutrients such as vitamins, minerals and fatty acids upon diseases such as arthritis, cancer, cardiovascular disease and diabetes, to discovering their potential cytotoxic effects upon cancerous cells (Goodman, 1997).

Today’s physicians receive little training in nutritional approaches to medicine and may therefore be unaware of potential underlying nutritional factors contributing to particular conditions, or of possible nutritional treatment approaches which have been shown to be therapeutically effective in treating a variety of illnesses. The general and specialist practitioner is rarely informed about nutritional approaches to health and disease and is therefore unable to inform the patients accurately about the possible therapeutic efficacy of nutritional supplements. As a result the extent of nutritional knowledge gleaned by the general practitioner is often confined to a few outmoded notions about what constitutes a ‘balanced diet’, recommended daily allowances (RDAs) of certain vitamins, and the levels required to prevent deficiency diseases such as beri beri and scurvy. Most physicians feel much more comfortable with drugs than foods.

### 3.8. Complementary and alternative medicine (CAM)

In many high-income countries utilization of complementary and alternative medicine (CAM) is becoming increasingly popular, with up to 65% of the population reporting that they have used this form of medicine (Harris, 2000; WHO, 2004). There is also considerable interest in CAM among primary care professionals, and many are already referring or suggesting referral (Astin, 1998b; van Haselen, 2004). International peer-reviewed specialist journals in CAM are emerging, and CAM studies already appear in established mainstream medical publications (Fontanarosa, 2001).

#### *3.8.1. Definition and classification of CAM*

CAM refers to a broad range of healing philosophies, approaches and therapies that exist largely outside the institutions where conventional health care is taught and provided. According to the definition used by the Cochrane Collaboration, ‘complementary and alternative medicine’ is a broad domain of healing resources that encompasses all health systems, modalities, practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas defined by their users as preventing or treating illness or promoting health and wellbeing. Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed’.

According to the US National Center for Complementary and Alternative Medicine (NCCAM), the term *complementary* conveys that these therapies are used in conjunction with, rather than as replacement for, a biomedical treatment, whilst the designator *alternative* conveys that a therapy is used in place of a biomedical treatment. The NCCAM classifies the major types of complementary and alternative medicine into five categories or domains:

- Alternative medical systems, which are built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach used in Europe. Examples include homeopathy, naturopathic medicine, traditional Chinese medicine and Ayurveda.
- Mind-body interventions designed to enhance the mind's capacity to affect bodily function and symptoms, such as meditation, prayer, mental healing, and therapies that use creative outlets such as art, music, or dance.
- Biologically based therapies, using substances found in nature, such as herbs, foods, and vitamins.
- Manipulative and body-based methods (based on manipulation and/or movement of one or more parts of the body), such as chiropractic or osteopathic manipulation, and massage.
- Energy therapies, involving the use of energy fields. These include biofield therapies (intended to affect energy fields that purportedly surround and penetrate the human body), such as qi gong, Reiki, and Therapeutic Touch, and bioelectromagnetic-based therapies (therapies involve the unconventional use of electromagnetic fields).

It is to be noted, however, that the term CAM does not fully correspond with holistic medicine. Although most CAM therapies are based on a holistic approach of the individual patient, some of them are simply techniques not recognised by the biomedical establishment. Also, some CAM practitioners may offer a treatment without a holistic assessment. Clearly, then, holism relates more to the individual practitioner's outlook than to the type of therapy.

#### *3.8.2. Reasons for popularity of CAM*

Several factors have been cited for the growth in the use of CAM (Astin 1998a, Jobst 1998,

Kaptchuk 1998, Mitzdorf 1999, Zollman 1999). The most important reason is the patient's dissatisfaction with biomedical treatment because it has been ineffective (the vast majority of patients consult CAM practitioners only after exhausting biomedical treatments, or with conditions where biomedicine has achieved only limited success or had been unable to offer any relief), has produced adverse side effects (a medication or treatment that is perceived to be worse than the condition for which biomedical care was sought), or is seen as impersonal and too technologically oriented (patients want to be given time and to be listened to, rather than being rushed by an overburdened conventional physician). Secondly, patients seek alternative therapies because they see them as less authoritarian with more personal autonomy, input and control over the decision-making regarding their care. They are also looking for a more intimate relationship with their health care providers. They want health professionals who will respect them as partners in their care and who see and understand them as whole people with complex lives, not just 'lesions' and lab values. Thirdly, CAM therapies are attractive because they are seen as more compatible with patients' values, world-view, spiritual/religious philosophy or beliefs regarding the nature and meaning of health and illness. These developments have been facilitated by the revolution in information technology, which is enabling easy access to sources of CAM information on the internet.

### *3.8.3. Individual treatment programme*

Since the holistic model views most illness and disease as the direct consequence of imbalance in the individual's environment, habits and/or way of living, which is potentially correctable, an important part of the practitioner's job is detective work: working in close collaboration with the patient in tracking down the pathogenic imbalance, and then with the aid of natural medicines and the patient's own commitment to change, facilitating the healing power of nature, *vis medicatrix naturae*, to restore the balance we call health (Millenson, 1995). CAM practitioners may therefore prescribe a package of care, which would include modification of lifestyle, dietary change, reduction or elimination of substance-abuse behaviours, acquisition of stress-reduction techniques and exercise as well as a specific treatment, such as a homeopathic prescription. Health psychology approaches are designed to modulate the stress response and improve health behaviours by teaching individuals more adaptive methods of interpreting life challenges and more effective coping responses. Since each person is unique, the treatment programme, to be most effective, must be individualized. Whenever possible, holistic medicine is collaborative and emphasises self-care and self-responsibility in health.

### *3.8.4 Optimum health is the aim*

It is the aim of CAM to bring about a condition of *optimum* health, not just the absence of symptoms of disease, as is the case with biomedicine. It is this focus upon health rather than disease which is largely responsible for the nature of holistic medicine and its effectiveness for disease prevention, early diagnosis, and the treatment of sub-clinical and chronic disease. The pre-disease state, the area between complete symptom-free wellbeing and actual disease is viewed as a lack of health needing attention. When a patient's disease becomes life threatening or highly infectious, then the patient is usually referred to biomedicine and its stronger methods. Even then, CAM has proven to be useful in palliation and quality of life aspects of conventional 'acute care'. Thus, the limitations of one system are often the strengths of the other (Fulder, 1998 Bates 2000).

### *3.8.5. Areas where CAM is inappropriate*

Since CAM is based upon restoring all of the patients' own natural systems for fighting disease to optimum efficiency, there are three areas in which such therapies may be ineffective and inappropriate. Firstly, any condition, which involves a degree of irreversible tissue damage or constitutional imbalance, whether from a disease, genetic cause or injury, may not be effectively treated by holistic therapies. Secondly, since holistic therapies depend upon optimum cellular nutrition, any disorder which interferes with the nutrient delivery system, from digestion and absorption through to transport into cells and mitochondria, may require a more interventionist approach. Finally, any life threatening condition may also require a biomedical interventionist approach.

### *3.8.6. Safety of CAM*

The risks of all CAM therapies compared with conventional prescription drugs of every kind is likely to be very low, but may vary from one CAM therapy to another. For instance, the incidence of adverse effects from acupuncture and homeopathy seem to be extremely low (NIH consensus statement, 1997; Dantas, 2000). Herbal medicines, although many of them have good safety profiles, may probably present a greater risk of adverse effects and interaction than any other CAM therapy (Vickers, 1999). The evidence regarding the nature and incidence of adverse effects of herbal medicines is highly incomplete (Ernst, 2004) and pharmacovigilance procedures for monitoring adverse effects are notably poor. Only relatively few clinical cases of interactions between herbal medicines and prescription drugs have been documented in the medical literature (Fugh-Berman, 2001), but it must be borne in mind that herbal medicines can be taken over an extended period of time, which provides the opportunity for enzyme induction and other mechanisms of interaction to take effect (Williamson, 2003).

Indirect risks may occur, for example, when CAM practitioners are not fully trained; when practitioners do not follow the professional code of ethics; when practitioners disregard possible interactions and contraindications; or when the treatment is not adjusted or modified according to the condition or constitution of the patient (WHO, 2004). Physicians who have taken training in a specific CAM therapy are particularly suitable to make a comparative assessment as to the therapeutic possibilities of CAM versus any necessity of biomedical intervention, which contributes to the safety of CAM practice.

### *3.8.7. Costs and cost-effectiveness of CAM*

Generally speaking, CAM modalities do not usually include the use of costly diagnostic procedures and drugs. Homeopathic or herbal medicines are generic, non-patented and non-patentable medicinal substances, which are produced at low costs. Further, the absence of significant side effects does not imply any costs associated with iatrogenic illness.

An analysis based on figures of the French Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés (CNAMTS, National Health Insurance Fund of Salaried Employees), in 1998 showed that primary care provided by homeopathic physicians was 50% less expensive than that by conventional physicians. Also, patients of homeopathic physicians had 50 % fewer sick-leave days than patients of conventional physicians (CNAMTS, 1998). A recent Belgian study (Van Wassenhoven, 2004) showed a similar pattern of savings in primary care provided by homeopathic physicians. Cost-effectiveness of homeopathy was shown by Heger (2003) in a multi-national, prospective cost-effectiveness study on homeopathic treatment

compared to conventional treatment in 1,000 patients with defined chronic illnesses, which demonstrated that complete recovery was significantly higher in patients treated with homeopathy than in those treated with conventional medicine. Other related studies by Vainchtock (2002), Becker-Witt (2003) and Trichard (2003) showed similar positive results for homeopathy.

Acupuncture in chronic headache disorders, particularly migraine has shown to be less expensive than other treatment modalities (Wonderling, 2004). Headache scores were better after acupuncture treatment; patients used fewer medications, had better health, fewer days off sick, and fewer visits to their general practitioner.

Although it seems likely that CAM could be effective in cutting healthcare costs, more information is needed on the short-term and long-term cost-effectiveness of specific CAM treatments for various conditions, different models of CAM practice, the clinical and financial impact of integrating CAM with conventional medicine, and the relative – both direct and indirect – costs of CAM treatments and conventional medical treatments.

### *3.8.8. Homeopathy as a typical example of CAM*

Homeopathy is the single alternative system of medical practice that has its roots in Europe<sup>7</sup>. It is based on the similarity principle, which means that substances capable of causing disorder on any level in healthy subjects can be used as medicines to remedy similar patterns of disorder experienced by people when they are ill. Skilled homeopathic prescribing requires that the characteristics of the chosen medicine should be as similar as possible to the characteristics of the illness in the patient. The more detailed the understanding of the symptom nuances of the patient, the more accurate the prescription. Thus, homeopathy is highly individualised and based upon a holistic assessment. The symptoms and signs, the emotional and physical reactions to the illness, the patient's personality, temperament, genetic predispositions and any strong family history of particular diseases may play an important part in medicine selection. In fact, homeopathy relates individual patterns of responding to environmental influences, infectious agents and potential stressors to specific homeopathic medicines that can remedy these susceptibility patterns.

Homeopathic medicines are aimed at improving the level of health by stimulating the self-regulatory mechanism. Improving the level of health implies reducing any disease process as well as the susceptibility to illness and disease. In principle, all illness can benefit from homeopathic treatment. The therapeutic possibilities, of course, depend on the extent to which the organism is able to recover. If the tissue damage has become irreversible, homeopathy will only have a palliative effect. The experience of homeopathic physicians is that usually many diseases, ranging from asthma to arthritis, pneumonia, migraine, allergies, liver diseases, depression etc. can be successfully treated with homeopathic medicines. Homeopathy offers therapeutic options where biomedical treatments have failed or plateaued, where they do not exist for the problem, where they are contraindicated or not tolerated. In fact, homeopathy can often be used as a first option in certain problems, keeping more costly and potentially toxic treatment as a second option.

Homeopathic medicines, in the European Union legally called homeopathic medicinal

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<sup>7</sup> Other alternative medical systems such as Traditional Chinese Medicine and acupuncture originate from China, ayurvedic medicine from India.

products, are preparations of substances with a botanical, chemical, mineral, zoological or biological origin. The doses used in homeopathy range between those that are similar in concentration to some conventional medicines and those that are highly diluted. They are prepared in accordance with a homeopathic manufacturing procedure described in the official pharmacopoeias currently used in the Member States, - the French, German, and increasingly, the European Pharmacopoeia. All EU Member States are obliged to register homeopathic medicines pursuant to Directive 2001/82/EC (veterinary use) and 2001/83/EC (human use) on the Community Code relating to medicinal products. The production of homeopathic medicines is subject to Good Manufacturing Practice rules. In general, homeopathic medicines are safe when used appropriately. While there are challenges generally regarding under-reporting, direct risks resulting from the use of homeopathic medicines seem to be extremely low (Dantas, 2000).

Homeopathic medicines are also becoming widely used in veterinary practice. For instance, in organic husbandry in the European Union, there is an obligation that, when animals become sick or injured, they should be treated preferentially with homeopathic or herbal medicinal products (Council Regulation 1804/1999/EC). This area is especially important in the livestock-farming sector, where homeopathic medicines may replace antibiotics, hormones and other medicines in some cases of infection, inflammatory disease or reproductive disorders, or may shorten the duration of antibiotic treatment. Thus consumers are more effectively protected, because homeopathic dilutions from  $10^{-6}$  M onwards will cause either no residue at all, or in the worst case, residues that are negligible, in the low ppb range.

### 3.9. Summarising the differences between the biomedical and holistic model

The following table shows the differences between the biomedical and holistic model:

Model	Holistic	Biomedical (western medicine)
Conceptualisation of human being	Organism as an adaptable, flexible and creative system interlinked with other systems	Mind and body separate identities; body as an object, a complex, but predictable biochemical machine
Emphasis	Health	Disease
Priority	Prevention	Repair, neutralisation, normalisation
Diagnostic focus	What made this person susceptible to disease? Causes on physical, emotional, social, mental, spiritual level	What is wrong in this person and has to be fixed? Localised tissue disruption & specific pathogen
Treatment approach	Mobilising and stimulating regenerative capacities ( <i>vis medicatrix naturae</i> ), restoring balance to the whole psychosomatic system	Eradicating, neutralising, fixing or managing a physical problem, intervening in disease pathway; symptomatic, mechanistic
Individualization/standardization	Individualization of care	Standardization of care
Long-term/short-term	A long-term focus on creating and maintaining health and well-being	Offensive intervention with emphasis on short-term results
Military metaphor for therapy	Stimulate the home forces	Search and destroy the invader

Patient/physician relationship	Authority and responsibility inherent in each individual; co-operative partnership; empowering	authority and responsibility inherent in physician, patient is a passive recipient of treatment, paternalistic, disempowering
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[Comparison of the holistic and biomedical model; adapted from Millenson and Davis-Floyd]

Since biomedicine is primarily focused on defeating disease by offensive intervention, destroying infectious agents or cancer cells or blocking specific pathophysiological pathways, it is clearly superior to holistic medicine for the treatment of serious trauma and life threatening diseases or conditions with irreversible tissue damage or other conditions requiring medical technology. In all other cases holistic medicine is much more effective by restoring the patients' own natural systems for fighting disease and maintaining health with the aid of natural medicines, modification of lifestyle, dietary change and health psychology approaches. While biomedicine tends to disempower patients by making their bodies passive recipients of technological treatments who are dependent on prescriptions drugs to manage their symptoms, holistic medicine is focused on strengthening and empowering patients, and on contributing to their autonomy.

Over the last decade a new model has emerged, which incorporates the best of biomedicine with the appropriate use of holistic approaches. This model is 'integrated medicine' and will be dealt with in the following chapter.

#### 4. Integrated medicine

Integrated medicine (or integrative medicine as it is called in the USA) – a term that emerged in the late 1990s – blends the best of conventional biomedicine with the holistic approach of Complementary and Alternative Medicine. It is not just about adding a bit of acupuncture to the aspirin, not simply '*combination medicine*', where 'elements' of CAM – after accumulation over time of good enough evidence – are selectively incorporated into comprehensive treatment plans alongside conventional methods of diagnosis and treatment, 'cherry picking' as it is termed. This way would result in assimilation, not in real integration.

##### 4.1. Integrated medicine, a comprehensive, patient-centred primary care system

Integrated medicine is a comprehensive, primary care system that emphasizes wellness and healing of the whole person as major goals, above and beyond suppression of a specific somatic disease (Bell, 2002). It involves patients and physicians working as partners in the effort to develop and implement a comprehensive treatment plan for issues that extend far beyond the immediate chief complaint and/or conventional diagnostic category (Bell, 2002) and to maintain health by paying attention to lifestyle factors such as diet, exercise, quality of rest and sleep, stress management, emotional wellbeing and the nature of relationships. Integrated medicine draws from biomedicine and CAM to facilitate healing and to empower the patient because healing is believed to originate within the patient rather than from the physician (Bell, 2002). The philosophy of integrated medicine is compatible with the WHO definition of health that equates health with wellbeing: 'Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity'.

With the increasing use of the holistic approach to illness, medicine will be paying more attention to the social and cultural environment of illness and the way humans negotiate through the sea of environmental, social, and informational influences (Fulder, 1998).

Healthcare today, says Fulder, might also benefit from an awareness of more meaningful ways of describing and measuring health offered by CAM, for example by including constitution and the quality of vitality. As mentioned earlier, giving importance to improving the level of health rather than defeating or suppressing disease is one of the most attractive features of many CAM therapies.

Integrated medicine implies that a competent practitioner will have an understanding of several different medical models including biomedicine and one or more CAM modalities. The basic medical principle, originally ascribed to Hippocrates, '*Primum non nocere*' (or: *Primum nil nocere*) meaning 'First, do no harm' should automatically ensure that the practitioner gives first preference to the safest and least toxic treatment options. In integrated medicine holistic wellness care would be first-line medicine, with the high-tech specialists serving as the line of last resort, especially in case of life threatening disease or the presence of irreversible tissue damage.

A more patient-centred model would shift the power from professionals to patients, creating the idea of 'expert patients', but still needs professional experts to develop knowledge and skills on their patient's behalf. This model of health care would create new priorities that could make the best of CAM and biomedical treatments available to patients safely and appropriately (Leckridge, 2004).

Although integrated medicine is the way of the future it must be ensured however, that those qualities of CAM, which are responsible for its longstanding safety and effectiveness, are fully retained. While there must be a degree of integration between CAM and biomedicine it must also be accepted that there is a fundamental difference between the underlying holistic and biomedical models. The holistic philosophy involves a mind-set or worldview that is much broader than modern biomedical thought and this difference must be respected and taught to succeeding generations.

It is essential that models are developed and evaluated for delivering integrated care in which respectful and professional collaborations between biomedical and holistic practitioners capitalise on the most effective and appropriate strategies to deliver high-level health care. There is no reason why every hospital should not have a ward dedicated to Traditional Chinese Medicine, another to homeopathy, another to ayurveda manned by traditional practitioners. These are pragmatic forms of collaboration, which represents 'integration' on a more equal professional footing. People should then be allowed to choose their medicine from the specialities, and if requested or necessary, a combination of them. The European Parliament stated (1997) that "it is increasingly widely held that different methods of treatment and different approaches to health and illness are not mutually exclusive, but can on the contrary be used to complement one another".

#### 4.2. Developments in the USA

In the USA the Consortium of Academic Health Centers for Integrative Medicine<sup>8</sup> (CAHCIM) includes 27 highly esteemed academic medical centers. It aims to "help transform medicine and healthcare through rigorous scientific studies, new models of clinical care, and innovative educational programs that integrate biomedicine, the complexity of human beings, the intrinsic nature of healing and the rich diversity of therapeutic systems". The Consortium

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<sup>8</sup> <http://www.imconsortium.org>

has issued the following statement:

“Integrative medicine is not a radical movement but it can produce major change. Its point is to position medicine to continue to build upon its fundamental platform of science but to reposition itself to create a health system which more broadly focuses on the well being of our patients as well as its practitioners. To do so, medical education and practice must:

- Refocus on the patient as a whole and the primacy of meaningful physician-patient relationships. More and more of the benefits of our health system will require changes in patient behaviour, i.e., modifying lifestyle as well as taking therapeutics correctly. Such changes will require far more meaningful physician-patient relationships and medical school curricula must incorporate strategies to reflect these needs.
- Involve the patient as an active partner in his/her care, with an emphasis on patient education concerning how they can best improve their health.
- Be open to understanding the benefits and limitations of conventional allopathic medicine and the realization that science alone will not effectively deal with all the complex needs of our patients. Many patients, particularly, those with chronic or life threatening conditions want access to CAM approaches. Our health system must rationally address these needs.
- Teach practitioners the fundamentals of CAM strategies including their underlying principles as well as evidence, or lack thereof, of efficacy.
- Advocate for sound clinical research to test the efficacy of CAM strategies.
- Use the best in scientifically based medical therapies whenever appropriate but provide compassion, attention to our patient’s spiritual and emotional needs as well as appropriate complementary and alternative approaches when they improve conventional medicine. Fundamentally, Integrative Medicine is meant to provide the best possible medicine/healthcare, for both doctor and patient, and the success of the movement will be signalled by dropping the adjective. It is our belief and recommendation that Integrative Medicine be a cornerstone of the urgently needed reconfiguration of our increasingly dysfunctional system of healthcare. The Integrative Medicine of today will simply be the medicine of the new century.”

## **5. Position of WHO and national authorities**

According to the World Health Organisation WHO, traditional medicine<sup>9</sup> (TM) and complementary and alternative medicine (CAM) account for a major part of the health care provided worldwide. In low- and middle-income countries, up to 80% of the population may rely on TM for their primary health care needs. In many high-income countries CAM utilization is becoming increasingly popular, with up to 65% of the population reporting that they have used this form of medicine (WHO, 2002).

### 5.1. Position of the World Health Organisation

#### *5.1.1. Traditional Medicine Strategy 2002-2005*

In response to the challenges posed by the widespread use of TM/CAM, the WHO in 2002 drew up its report ‘Traditional Medicine Strategy 2002-2005’, describing its first global

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<sup>9</sup> The WHO uses the term ‘traditional medicine’ when referring to Africa, Latin America, South-East Asia and/or the Western Pacific, whereas ‘CAM’ is used when referring to Europe and/or North America (and Australia). When referring in a general sense to all of these regions, the WHO uses the comprehensive term TM/CAM.

strategy on traditional and alternative medicine, which ‘provides a framework for policy to assist countries to regulate traditional or complementary/alternative medicine (TM/CAM) to make its use safer, more accessible to their populations and sustainable’. It mentions specific objectives to support countries to:

- integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes
- promote the safety, efficacy and quality of TM/CAM by expanding the knowledgebase on TM/CAM, and by providing guidance on regulatory and quality assurance standards
- increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations
- promote therapeutically sound use of appropriate TM/CAM by providers and consumers.

A comprehensive overview of the WHO Traditional Medicine Strategy 2002-2005 including its objectives, components and expected outcomes, can be found in the following table:

**WHO Traditional Medicine Strategy 2002–2005 — objectives, components and expected outcomes**

<b>Objectives</b>	<b>Components</b>	<b>Expected outcomes</b>
<b>POLICY:</b> Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes	<b>1. Recognition of TM/CAM</b> Help countries to develop national policies and programmes on TM/CAM	1.1 Increased government support for TM/CAM, through comprehensive national policies on TM/CAM 1.2 Relevant TM/CAM integrated into national health care system services
	<b>2. Protection and preservation of indigenous TM knowledge relating to health</b> Help countries to develop strategies to protect their indigenous TM knowledge	2.1 Increased recording and preservation of indigenous knowledge of TM, including development of digital TM libraries
<b>SAFETY, EFFICACY AND QUALITY:</b> Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge-base on TM/CAM, and by providing guidance on regulatory and quality assurance standards	<b>3. Evidence-base for TM/CAM</b> Increase access to and extent of knowledge of the safety, efficacy and quality of TM/CAM, with an emphasis on priority health problems such as malaria and HIV/AIDS	3.1 Increased access to and extent of knowledge of TM/CAM through networking and exchange of accurate information 3.2 Technical reviews of research on use of TM/CAM for prevention, treatment and management of common diseases and conditions 3.3 Selective support for clinical research into use of TM/CAM for priority health problems such as malaria and HIV/AIDS, and common diseases
	<b>4. Regulation of herbal medicines</b> Support countries to establish effective regulatory systems for registration and quality assurance of herbal medicines	4.1 National regulation of herbal medicines, including registration, established and implemented 4.2 Safety monitoring of herbal medicines and other TM/CAM products and therapies
	<b>5. Guidelines on safety, efficacy and quality</b> Develop and support implementation of technical guidelines for ensuring the safety, efficacy and quality control of herbal medicines and other TM/CAM products and therapies	5.1 Technical guidelines and methodology for evaluating safety, efficacy and quality of TM/CAM 5.2 Criteria for evidence-based data on safety, efficacy and quality of TM/CAM therapies
<b>ACCESS:</b> Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations	<b>6. Recognition of role of TM/CAM practitioners in health care</b> Promote recognition of role of TM/CAM practitioners in health care by encouraging interaction and dialogue between TM/CAM practitioners and allopathic practitioners	6.1 Criteria and indicators, where possible, to measure cost-effectiveness and equitable access to TM/CAM 6.2 Increased provision of appropriate TM/CAM through national health services 6.3 Increased number of national organizations of TM/CAM providers

	<b>7. Protection of medicinal plants</b> Promote sustainable use and cultivation of medicinal plants	7.1 Guidelines for good agriculture practice in relation to medicinal plants 7.2. Sustainable use of medicinal plant resources
<b>RATIONAL USE:</b> Promote therapeutically sound use of appropriate TM/CAM by providers and consumers	<b>8. Proper use of TM/CAM by providers</b> Increase capacity of TM/CAM providers to make proper use of TM/CAM products and therapies	8.1 Basic training in commonly used TM/CAM therapies for allopathic practitioners 8.2 Basic training in primary health care for TM practitioners
	<b>9. Proper use of TM/CAM by consumers</b> Increase capacity of consumers to make informed decisions about use of TM/CAM products and therapies	9.1 Reliable information for consumers on proper use of TM/CAM therapies 9.2 Improved communication between allopathic practitioners and their patients concerning use of TM/CAM

### *5.1.2. Resolution on Traditional Medicine and CAM*

In May 2003 WHO General Assembly adopted a resolution on Traditional Medicine and Complementary and Alternative Medicine, which **urges** Member States, among other items,

- to adapt, adopt and implement, where appropriate, WHO’s traditional medicine strategy as a basis for national traditional medicine programmes or work plans;
- where appropriate, to formulate and implement national policies and regulations on traditional and complementary and alternative medicine in support of the proper use of traditional medicine, and its integration into national health-care systems, depending on the circumstances in their countries;
- to provide adequate support for research on traditional remedies;
- to promote and support, if necessary and in accordance with national circumstances, provision of training and, if necessary, retraining of traditional medicine practitioners, and of a system for the qualification, accreditation or licensing of traditional medicine practitioners;
- to provide reliable information on traditional medicine and complementary and alternative medicine to consumers and providers in order to promote their sound use.

### *5.1.3 Consumer guidelines for Traditional Medicine and CAM*

In order to develop information to meet the needs of consumers, the WHO, in 2004, developed Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine. These guidelines ‘provide governments and other stakeholders with an overview of the general principles and activities necessary for the development of reliable consumer information’. The document is also meant to be ‘a useful reference to consumers in guiding them on the information they need to have in order to choose a TM/CAM therapy that is safe and effective’.

### *5.1.4. Report on diet, nutrition and the prevention of chronic diseases*

The WHO report on ‘Diet, nutrition and the prevention of chronic diseases’ published in 2003 describes the need for action to strengthen control and prevention measures to counter the spread of the chronic diseases. It is intended to support the Member States in addressing food and nutrition policy, health promotion, and strategy for the control and prevention of chronic diseases, as well as other related topics such as promoting healthy ageing and tobacco control.

## 5.2 Position of the US government

### *5.2.1. National Center for Complementary and Alternative Medicine*

Some national authorities have taken the growing demand for CAM seriously, especially the USA. In the USA in 1998 the Congress established the National Center for Complementary and Alternative Medicine (NCCAM)<sup>10</sup> at the National Institutes of Health that is charged to ‘conduct basic and applied research (intramural and extramural), research training, and disseminate health information and other programmes with respect to identifying, investigating, and validating CAM treatments, diagnostic and prevention modalities, disciplines and systems’.

#### *5.2.2. White House Commission*

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established in March 2000 to address issues related to access and delivery of CAM, priorities for research, and the need for better education of consumers and health care professionals about CAM. The Commission’s primary task is to provide, through the Secretary of Health and Human Services, legislative and administrative recommendations for ensuring that public policy maximizes the potential benefits of CAM therapies to consumers. Specifically, the Commission's mission was to address:

- education and training of health care practitioners in CAM;
- coordination of research to increase knowledge about CAM products;
- provision of reliable and useful information on CAM to health care professions, and,
- provision of guidance on the appropriate access to and delivery of CAM.

The NCCAM’s annual budget was \$ 117.7 million (approx. € 100 million) in fiscal year 2004, which is 0.4 % of the total budget of the National Institutes of Health.

In its first 5-year strategic plan 2001-2005 ‘Expanding horizons of health care’ the NCCAM outlined its vision and goals, and identified four strategic areas:

- Investing in research by encouraging and supporting CAM research projects, and also by building research capacity and infrastructure, both intramurally and extramurally;
- Training CAM researcher by providing appropriate career development opportunities; by increasing the knowledge, experience, and capacity of CAM practitioners to conduct rigorous research; and by enhancing conventional practitioners’ and researchers’ knowledge and experience in specific CAM areas;
- Expanding outreach by a variety of methods, media, and technologies to provide a timely source of evidence-based, CAM information;
- Facilitating integration between CAM and conventional healthcare professionals resulting in interdisciplinary teams to deliver an expanded repertoire of safe and effective treatments that include a focus on the whole person.

#### 5.3. Position of the UK government

The UK House of Lords Select Committee on Science and Technology in their 2000 report on CAM note that public satisfaction with CAM is high and use of CAM is increasing, and that in the interests of public safety the complementary medicine sector should be properly regulated. That training for CAM professionals should be standardized and independently accredited, and that registered conventional health professionals should become more familiar with CAM. The report made some recommendations as to how research could be encouraged, including pump-priming by the National Health Service and Medical Research Council (see chapter 6).

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<sup>10</sup> More information about the NCCAM can be found on its website <http://nccam.nih.gov/>

#### 5.4. Urge for policies on CAM in other EU member states

To ensure safety and efficacy of CAM treatments for consumers and patients, the current situation in many Member States, where the practice of CAM is not legally recognized or defined and its regulation varies from jurisdiction to jurisdiction, needs improvement. The time has come that EU Member States adopt policies in order to define the role of CAM in national health care delivery systems. These policies can also ensure that the necessary regulatory and legal mechanisms are in place for promoting and maintaining good practice, that access to CAM is equitable and that the authenticity, safety and efficacy of CAM treatment are assured. Their policies should therefore cover legislation and regulation for CAM medicines and practice as well as education, training and licensing of practitioners.

### **6. Research into CAM**

#### 6.1. Reasons for CAM research being disadvantaged

Research in CAM has been seriously hampered by a lack of research infrastructure and funding, lack of research expertise among CAM practitioners, lack of appropriate research models and strategies as well as the scepticism of the scientific community. Whilst CAM may improve health, reduce disease, and reduce health costs, industry alone cannot be expected to support the research to answer these questions. This is partly because of the lack of financial incentives for industry, and partly because, like mainstream medical research, there is a social responsibility for government to fund such research. There is a huge disparity between public funding for conventional drug research and that for CAM research. In the United Kingdom 0.08 % of the total research budget is being spent on CAM (Ernst, 1999) and it may be assumed that this percentage is not much higher in other countries. Funding by the industry is limited by the fact that homeopathic and herbal medicines are generic and cannot be patented; thus there are no large profits to be made from investments in research as for many new biomedical drugs.

#### 6.2. Research infrastructure

Approaches in the USA where ‘seed’ funding and dedicated funding were available provided some impetus to establish and continue an effective CAM research program. To date the NCCAM has funded 10 university-based centres for research on CAM. The lessons of NCCAM show that, if funds are there, experienced researchers will apply for them, and with sufficient investment high-quality research in non-conventional medicine can be achieved.

In their report on CAM the UK House of Lords Select Committee on Science and Technology also took the position that something must be done to build up the research capacity in CAM. They recommended, that funding research ‘should be boosted in order to create a few centres of excellence for conducting CAM research, integrated with research into conventional healthcare. This will also help to promote research leadership and an evaluative research culture in CAM. Such funds should support research training fellowships and a limited number of high-quality research projects. This initiative should be sufficient to attract high-quality researchers and to enable them both to carry out large-scale studies and to continue to train CAM researchers in this area within a multi-disciplinary environment. We believe ten years would be sufficient for the pump-priming initiative as, for example, in the case of some research programme grants and various training and career development awards available in conventional medicine.’ In their opinion ‘it will not be long before CAM research will be able to compete against other bids for funds in a way that it cannot currently do’. A central

mechanism for co-ordinating, advising, and training on research into complementary and alternative medicine was suggested, using government and charitable resources. Secondly, it asked the government to provide dedicated research funding to create centres for complementary medicine research. As a result of this report, the British government in 2003 granted 1.3 million Pound Sterling (€1.9 million) for 5 research projects in CAM.

In three other European countries (Denmark, Norway and the Netherlands) a modest start has been made to promote CAM research. The Danish Parliament in December 1998 granted 3 million Danish crowns (€ 400,000) for the establishment of a ‘Research and Science Centre for alternative medicines’. The Norwegian Parliament granted 1.5 million Norwegian crowns (€ 200,000) annually over 4 years (1993-1997) to CAM research which in 1998 was increased to 2 million crowns (€ 260,000) annually. The Dutch government in 2004 granted €190,000 to develop adequate research methodology in CAM, to set up training facilities for CAM researchers and to mature existing research questions for mainstream funding.

### 6.3. COST-Action B4

In June 1999 the final report ‘COST<sup>11</sup> Action B4 – Unconventional medicine<sup>12</sup>’ and its supplement was presented to the European Commission. This comprehensive report identifies common recommendations for basic and clinical research, constraint analysis, education and training, ethics and safety. It includes (a) guidelines for high-quality research in CAM, (b) an overview of the currently conducted research projects, and (c) a section containing all relevant basic research literature. The report has set out to demonstrate what is in the best interests of European citizens regarding the use of CAM within health care delivery in Europe.

One of the recommendations in the COST Action B4 report is to establish an independent ‘European Healthcare Office’ in collaboration with experts from biomedicine and CAM to (a) recommend guidelines for research in unconventional medicine, and (b) consider a pan-European strategy to help training of researchers. In addition, they recommended the establishment of a ‘pan-European advisory group on healthcare options in unconventional medicine’ to (a) provide reliable scientific information and (b) offer practical research and education advice. The management committee recommends that (a) new European research programmes and initiatives be developed and that (b) consideration be given to the funding of unconventional medicine research. In spite of these recommendations the European Commission to date has failed to respond.

### 6.4 Widespread use legitimates funding

Generally speaking, in contrast to the widespread use of CAM among European citizens, to date there is a negligible amount of funding for research in this area by the European Union and EU Member States. At the instance of the European Parliament and the Council of Ministers, the European Commission included research in CAM (non-conventional medicine) into the 5<sup>th</sup> and 6<sup>th</sup> RTD Framework Programme. Since CAM had no dedicated funds, research protocols from the field of non-conventional medicine had to compete with mainstream

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<sup>11</sup> COST (= Co-operation in Science and Technology is a framework for scientific and technical co-operation, allowing co-ordination of nationally funded research on a European Union level) comprises all EU Member States and 13 other European countries. COST-B4 relates especially to co-operation of research activities on the medical, cultural, psychological, legislative and economic aspects of non-conventional medicine.

<sup>12</sup> Unconventional medicine is synonymous with CAM

medical protocols. To date, the European Commission has taken the position that there is no justification for a different approach to research in CAM, compared to biomedical therapies, that they welcome applications for support to evaluate CAM therapies, but that they will be judged case-by-case on their own merits, in competition with other calls on research funds. The current limited research infrastructure and experience in the field of CAM, however, greatly hampers competition with biomedical research proposals. Therefore, without the development of a research infrastructure, which reflects the actual prevalence and relevance of CAM in Europe, an adequate evaluation of this huge field is not possible. The European Union and its Member States are recommended to provide adequate support, i.e. dedicated funding, for further research on the safety and efficacy of CAM. Public and private resources should be increased to strengthen the infrastructure for CAM research and research training at conventional medical and CAM institutions and to expand the cadre of basic, clinical, and health services researchers who are knowledgeable about CAM and have received rigorous research training.

Research in CAM should not just investigate the efficacy of a complementary set of instruments in the medical bag. Research on the role of CAM in wellness and health promotion, the application of CAM principles and practices, the mechanisms of action of individual CAM therapies, including patterns of response to treatment, and the role of CAM practitioners in the management of chronic disease should be expanded. New and innovative CAM research is necessary on core questions posed by frontier areas of scientific study associated with CAM that might expand our understanding of health, illness/disease and healing (mechanisms facilitating self-healing, factors contributing to ‘spontaneous remissions’). Public and private resources should be used to support, conduct, and update systematic reviews of the peer-reviewed research literature on the safety, efficacy, effectiveness, and cost-benefit of CAM practices and products.

The desirable way forward implies that the Member States and the European Union realize that public sources of funding should be responsive to patient need, and therefore more should be made available to develop research structures within holistic (non-conventional) medicine. Without dedicated funds, holistic medicine will struggle to attract high-quality researchers and it will be hard to build the infrastructure for the research that needs to be done in this area for the benefit of European citizens.

## **7. Consequences for the medical curriculum**

Introducing CAM into the medical curriculum will produce fundamental changes in the way physicians are trained because integrated medicine is not just about teaching doctors to use herbs instead of drugs. It is about restoring core values, which have been eroded by social and economic forces (Rees).

Both the European Parliament and the Council of Europe have identified the importance of training medical graduates, so that their knowledge and understanding of CAM enables them to have informed discussions with their patients. Also more and more medical associations emphasise the need for medical practitioners to obtain a basic understanding of CAM through undergraduate, vocational and continuing education. The education and training of CAM and conventional practitioners should be designed to ensure public safety, improve health, and increase the availability of qualified and knowledgeable CAM and conventional practitioners and enhance the collaboration among them.

Since lifestyle factors such as diet and nutrition exert their effects by optimising vital energy and the body's own restorative mechanisms these facts must clearly be given much greater priority in medical training. Medical students are to be familiarised with the potential uses of CAM, the procedures involved, their potential benefits, and their main strengths and weaknesses within the existing undergraduate curricula. Over the past few years there has been a major increase in courses familiarizing students with CAM. A review by the University of Genoa (Barberis, 2001) revealed that 40% of the responding medical faculties at European universities provide teaching courses involving CAM, although there is a wide variation between medical schools in students' level of exposure to these therapies.

## **8. Conclusions and recommendations**

As Commissioner Byrne stated in 2004, Europe should take positive action to avoid ill health in the first place, and pro-active, forward looking, long-term measures to promote good health are needed. He rightly argued that the time has come for a change of emphasis from treating ill health to promoting good health. As he said, 'Imagine the day when Europe makes a real shift from a focus on illness to a focus on health' (Byrne, 2004).

### 8.1. Fundamental change

Evidence cited throughout this document has established beyond question both the urgency of, and the depth of, the need for change to the current EU healthcare system. A fundamental change is urgently required if we are to safeguard public health. Such changes cannot occur if medicine retains its current form. Integrated medicine, whereby medicine incorporates the many strengths of CAM, especially its focus on seeking optimum health, is essential.

### 8.2. Towards a patient oriented integrated system

If the EU wants to deliver high quality care on all levels, not merely technological and pharmaceutical, in the 21<sup>st</sup> century, an effective, safe, patient orientated integrated system of health care is needed where both the biomedical and the holistic model are used primarily within their particular areas of expertise. Toxic symptom concealing drugs and hazardous invasive procedures should be reserved for trauma or life threatening diseases and should, in most cases, not be a first treatment option for illness. Determination to 'do no harm' should be uppermost in the minds of all physicians and should automatically ensure that physicians will give first preference to the safest and least toxic treatment options.

If the EU is to help its citizens achieve good health, 'it must address the behavioural, social and environmental factors that determine health' and 'we need to promote health through all policies' (Byrne, 2004). Therefore, it is necessary for physicians to broaden their understanding of how different systems within the mind/body interact and fully embrace the evidence demonstrating that taking care of the mental, emotional and spiritual aspects of a patient's life is just as important as correcting physiological derangements, for all these aspects are inseparable. Such notions are not fanciful, but based on very sound scientific evidence.

All the major CAM systems approach illness first by trying to support and induce the self-healing process of the person. If recovery can occur from this, the likelihood of adverse

effects and the need for high-impact, high-cost intervention is reduced. It is this orientation towards self-healing and health promotion – salutogenesis rather than pathogenesis, or improving health rather than defeating disease – that makes CAM approaches especially appropriate.

The European Union policy ‘must focus more on the citizens’ and ‘must empower citizens to make healthy choices and involve them in policy-making from the start’ (Byrne, 2004). Nowadays, increasing numbers of patients are looking for alternatives to biomedicine. CAM has the potential to humanise modern medicine and widen its vision beyond disease to health and wellbeing in its widest sense. CAM is empowering because it encourages people to use and to recognise their own self-healing abilities and to develop more active approaches to life beyond the classic active/passive relationship of the biomedical encounter. Integrated medicine, which as the best of both worlds maximises both safety and choice, is a new perspective on how to achieve good health for all as it was confirmed in an Editorial in the British Medical Journal (Rees, 2001). European healthcare should offer integrated medicine, especially if the EU wants to be ‘a catalyst for change geared towards achieving good health’ as Commissioner Byrne recently said.

### 8.3. Recommendations COST B4 Action Plan

The general recommendations from the Management Committee of the COST B4 Action on Unconventional Medicine (= CAM) in their 1998 report – published by the Directorate General Science, Research and Development of the European Commission – are still highly relevant and await implementation. They are as follows:

1. The management committee recognizes that significant numbers of European citizens are making frequent use of unconventional medicine. This makes it essential that:

- there is a defined minimum European standard of medical knowledge among unconventional therapists
- there is further support, funding and co-ordination of national and international research in unconventional medicine
- medical practitioners are informed and are able to discuss unconventional medicine options with their patients

2. The management committee recommends that national and international agencies do all they can to ensure that the unconventional medical treatment people receive is safe and effective. To do this the management committee proposes the following:

- The creation of an independent European Healthcare Office in collaboration with experts from conventional or unconventional medicine where appropriate to:
  - recommend guidelines for research in unconventional medicine
  - consider a pan-European strategy to help training of researchers
  - develop a system of registration of practitioners
  - establish criteria for the validation of practice
- The establishment of a pan-European advisory group on healthcare options in unconventional medicine to:
  - provide reliable scientific information
  - offer practical research and education advice
  - liaise with patients, practitioners, health authorities and government agencies
  - ensure that existing European guidelines on ethical standards of practice in research are applied to those working in the unconventional medicine field

3. The management committee is aware that research evidence in unconventional medicine is still scarce. While recognizing that more research is now being carried out each year, claims made in this field are often anecdotal, exaggerated or unsubstantiated. The management committee recommends that:

- new European research programmes and initiatives be developed
- consideration be given to funding of unconventional medicine research

4. The management committee recognizes that market forces are determining current trends in unconventional medicine. There is a need to balance the individuals' freedom of choice' with the duty to protect them from harm. In the light of the above the management committee recommends that:

- unconventional medicine practitioners be subject to the same or similar codes of conduct, discipline and accountability as other medical practitioners
- new therapies or healthcare treatments be subject to the normal process of appraisal through research approved by ethical committees prior to availability in general medical practice
- evidence-based research is used to inform practitioners on appropriate use of unconventional medicine where possible.

5. The management committee is conscious that different countries have different legal perspectives in this field. It recommends:

- a minimum standard for accreditation and certification for all practitioners of therapies

6. The management committee, appreciates the help of the European Commission during its deliberations, recommends that:

- continued support be given to initiatives in the field of unconventional medicine, through the COST mechanism and/or other Community programmes that may be appropriate.

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– The Karlsruher Virtueller Katalog KVK

<http://www.ubka.uni-karlsruhe.de/hylib/en/kvk.html>

– WHO (for WHO publications)

<http://www.who.int/en/>

– Ingenta

<http://www.ingentaconnect.com/>