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LO STATUS GIURIDICO DELLE MEDICINE NON CONVENZIONALI IN ITALIA E IN ALTRE NAZIONI OCCIDENTALI

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RIASSUNTO

Viene descritto lo status delle Medicine Non Convenzionali in alcune Nazioni dell'Europa Occidentale in relazione alle Direttive della Comunità Europea, alle linee guida dell'Organizzazione Mondiale della Sanità e alla situazione esistente negli Stati Uniti d'America.

Parole chiave: Medicine Non Convenzionali, MNC

SUMMARY

Review of the status of Complementary and Alternative Medicine according to the system of Laws of different countries of West Europe, if accordingly with European Parliament resolutions and related with the guidelines of World Health Organization and the present situation of CAM in the United States of America.

Key words: Complementary and Alternative Medicine, Non Conventional Therapies, CAM, NCT.

INTRODUZIONE

Questa analisi prende in considerazione lo status giuridico delle Medicine Non Convenzionali delle Nazioni la cui legislazione sia di particolare rilevanza o che sia sottoposta a recente revisione ovvero legislazione di Nazioni che sono il riferimento culturale e scientifico storico delle Medicine Non Convenzionali di origine occidentale e le eventuali concordanze o adeguamenti con quanto finora il Parlamento Europeo ha deliberato sull'argomento, con quanto indicato dall'Organizzazione Mondiale della Sanità, e si prenderà in esame lo status delle Medicine Non Convenzionali negli Stati Uniti d'America.

PARLAMENTO EUROPEO

Il Parlamento Europeo nella sessione plenaria del 29.5.1997 con la Risoluzione n. 75 *(Gazzetta Ufficiale n. C 182 del 16/06/1997)* e il Consiglio d'Europa con la Risoluzione n. 1206 del 4 novembre 1999 deliberarono di demandare alla Commissione Europea di elaborare uno studio approfondito per quanto concerne l'innocuità, l'efficacia, il campo d'applicazione e il carattere integrativo o alternativo di ciascuna Medicina Non Convenzionale, nonché uno studio comparativo dei sistemi giuridici nazionali esistenti cui sono soggetti coloro che praticano medicine non convenzionali.

Venne anche chiesto alla Commissione, qualora i risultati dei relativi studi lo avessero consentito, di impegnarsi in un processo di riconoscimento delle Medicine Non Convenzionali e, a tal fine, di adottare le misure necessarie per favorire l'istituzione di comitati ad hoc.

Il Parlamento Europeo chiese infine alla Commissione di presentare una proposta di linea direttrice sugli integratori alimentari, che spesso si collocano al confine tra il prodotto dietetico e il medicinale.

La risoluzione deliberata dal Parlamento Europeo col nome di:

"Statuto delle Medicine Non Convenzionali" così recita:

Il Parlamento europeo,

- vista la proposta di risoluzione degli onn. Pimenta, Dell'Alba, Díez De Rivera, Crowley, Ewing, González Álvarez e Plumb sulla medicina complementare (o alternativa) (B4-0024/94),

- visto il suo parere del 13 giugno 1991 sulla proposta della Commissione al Consiglio per una direttiva che amplia il campo di applicazione delle direttive 65/65/CEE e 75/319/CEE per il ravvicinamento delle disposizioni legislative, regolamentari e amministrative relative ai medicinali e che fissa disposizioni complementari per i medicinali omeopatici (GU C 183 del 15.7.1991, pag. 318.),

- vista la direttiva 92/73/CEE del Consiglio che amplia il campo di applicazione delle direttive 65/65/CEE e 75/319/CEE concernenti il ravvicinamento delle disposizioni legislative, regolamentari e amministrative relative ai medicinali e che fissa disposizioni complementari per i medicinali omeopatici ((GU L 297 del 13.10.1992, pag. 8.)),

- viste le linee di bilancio B6-8332 del bilancio dell'Unione europea per l'esercizio 1994, B6-7142, penultimo trattino, del bilancio per l'esercizio 1995, B6-7142, quarto e quinto trattino, del bilancio per l'esercizio 1996, che prevede l'importo di 1.000.000 ECU per «ricerche sull'efficacia di metodi terapeutici quali la chiropratica, l'osteopatia, l'agopuntura, la naturopatia, la medicina cinese, la medicina antroposofica, la fitoterapia, ecc.»,

- visti la relazione della commissione per la protezione dell'ambiente, la sanità pubblica e la tutela dei consumatori e il parere della commissione giuridica e per i diritti dei cittadini (A4-0075/97),

A. considerando che una parte della popolazione degli Stati dell'Unione europea fa ricorso a determinate medicine e terapie non convenzionali e ritenendo irrealistico ignorare tale dato di fatto,

B. considerando l'opinione sempre più ampiamente condivisa, anche da numerosi medici, secondo cui diversi metodi di trattamento o diversi approcci

alla salute e alla malattia non si escludono reciprocamente ma possono essere invece utilizzati in modo complementare,

C. considerando l'importanza, da un lato, di garantire ai pazienti la più ampia libertà possibile di scelta terapeutica - assicurando loro il più elevato livello di sicurezza e l'informazione più corretta sull'innocuità, la qualità, l'efficacia e il rischio eventuale delle cosiddette medicine non convenzionali - e, dall'altro, di proteggerli da persone non qualificate,

D. considerando che l'insieme dei sistemi medici e delle discipline terapeutiche riuniti nella denominazione «medicine non convenzionali» hanno in comune il fatto che la loro validità non è riconosciuta o lo è solo parzialmente; che si può qualificare di «alternativo» un trattamento medico o chirurgico in grado di sostituirne un altro e di «complementare» un trattamento utilizzato a integrazione di un altro; che risulta equivoco parlare di disciplina medica «alternativa» o «complementare», nella misura in cui solo il contesto preciso nel quale la terapia è utilizzata permette di determinare se essa sia all'occorrenza alternativa o complementare; che una disciplina medica alternativa può altresì essere complementare; che nella presente risoluzione il termine «medicine non convenzionali» riassume le nozioni di «medicine alternative», «medicine dolci» e «medicine complementari», utilizzate indistintamente in taluni Stati membri per designare le discipline mediche diverse dalla medicina convenzionale,

E. considerando che il medico può utilizzare, al fine della massima tutela della salute dei propri pazienti, tutti i mezzi e tutte le conoscenze nell'ambito di qualsiasi tipo di medicina secondo scienza e coscienza,

F. considerando che esiste un largo spettro di discipline mediche non convenzionali e che talune di esse - come in particolare la chiropratica, l'omeopatia, la medicina antroposofica, la medicina tradizionale cinese (compresa l'agopuntura), lo shiatsu, la naturopatia, l'osteopatia, la fitoterapia, ecc. - beneficiano di una forma di riconoscimento giuridico in taluni Stati

membri e/o di una struttura organizzativa sul piano europeo (formazione di base comune, codice deontologico ...); considerando però che soltanto alcune di esse soddisfano i seguenti criteri: una forma di riconoscimento giuridico in taluni Stati membri, una struttura organizzativa sul piano europeo e una disciplina di autoregolamentazione,

G. considerando il trattato CE, in particolare il titolo III, articoli 52-66, concernenti la libera circolazione delle persone e la libertà di stabilimento; ritenendo che l'eterogeneità in materia di status e di riconoscimento di ciascuna delle discipline mediche non convenzionali in seno all'Unione costituisca un ostacolo a tali libertà; che la libertà di esercitare di cui godono attualmente taluni terapeuti sanitari nei loro Stati non dovrebbe essere limitata in nessun caso da una modifica dello statuto o dello stato di riconoscimento di tali discipline a livello europeo e che da tutto ciò non dovrebbe derivare alcuna restrizione della libertà di scelta terapeutica dei pazienti riguardo ai trattamenti medici non convenzionali; considerando le disposizioni del trattato per gli Stati membri, e più precisamente quelle previste dall'articolo 57, paragrafi 1, 2 e 3,

H. considerando che un'evoluzione si è già chiaramente manifestata, sia grazie all'adozione in taluni Stati membri di legislazioni nazionali che liberalizzano l'esercizio delle medicine non convenzionali, riservando contemporaneamente taluni atti specifici a terapeuti autorizzati (legge approvata il 9 novembre 1993 dal Senato olandese e denominata «Beroepen in de individuele gezondheidszorg»), sia attraverso l'adozione di una regolamentazione specifica (legge sugli osteopati del 1993 e legge sui chiroterapeuti del 1994 nel Regno Unito, legislazione sulla chiropratica in Danimarca nel 1991, in Svezia nel 1989 e in Finlandia), l'ufficializzazione della formazione (la chiropratica nel Regno Unito e negli Stati nordici) oppure l'inserimento dei medicinali nella farmacopea (medicina antroposofica in Germania),

I. considerando che una legislazione europea in materia di statuto e di esercizio delle medicine non convenzionali potrebbe costituire una garanzia per i pazienti e che ciascuna disciplina dovrebbe essere in grado di organizzare la professione a livello europeo (codice deontologico, registro della professione, criteri e grado di formazione),

J. considerando che è necessario individuare chiaramente ciascuna delle discipline mediche non convenzionali; che a tal fine occorre proseguire gli studi clinici, la valutazione dei risultati del trattamento, gli studi fondamentali (meccanismi d'azione) e altri studi scientifici o ricerche accademiche atti a valutare l'efficacia delle terapie adottate, partendo dal presupposto che tale valutazione deve aver luogo secondo le metodologie abituali in ogni terapeutica umana, ovvero quelle basate sulle conoscenze scientifiche del momento, e in particolare quelle specifiche delle scienze biologiche e statistiche,

K. considerando che la regolamentazione e il coordinamento dei criteri di formazione imposti ai terapeuti di discipline mediche non convenzionali costituirebbe una garanzia indispensabile per i cittadini; considerando che è imperativo, sia nell'interesse dei pazienti che in quello dei terapeuti, che questa armonizzazione sia fatta a un alto livello di qualifiche e che sia richiesto in ogni caso l'ottenimento di un diploma di stato che risponda alle esigenze specifiche di ciascuna disciplina; considerando che i livelli di formazione devono essere adeguati ai principî medico-sanitari generali richiesti da ogni atto terapeutico nonché alle specificità delle diverse discipline mediche non convenzionali,

L. considerando che la formazione dei terapeuti della medicina convenzionale dovrebbe comprendere anche un'iniziazione a talune discipline mediche non convenzionali,

M. considerando che per dare ai terapeuti la possibilità di esercitare correttamente la loro professione e contemporaneamente garantire ai pazienti

un'attenta valutazione dei medicinali non convenzionali la farmacopea europea deve poter includere l'intera gamma dei prodotti farmaceutici e di erboristeria utilizzati nella medicina non convenzionale; che, per le stesse ragioni, è necessario rivedere le direttive 65/65/CEE, 75/319/CEE e 92/73/CEE, nonché il regolamento (CEE) 2309/93 che istituisce l'Agenzia europea di valutazione dei medicinali, garantendo così ai pazienti qualità e innocuità delle medicine non convenzionali,

N. considerando che nella sua risoluzione 350/05 del 20 dicembre 1995 relativa ai preparati a base di piante medicinali ((GU C 350 del 30.12.1995, pag. 6.)) il Consiglio invita la Commissione a chiarire il «regime giuridico dei preparati a base di piante medicinali, tenuto conto delle disposizioni comunitarie in materia di specialità medicinali» e a studiare «le condizioni specifiche necessarie per garantire la tutela della sanità pubblica»,

O. considerando l'esigenza di dimostrare la qualità, l'efficacia e l'innocuità dei prodotti terapeutici in esame e di prevedere la pubblicazione di monografie su ciascun prodotto,

P. considerando che, tenuto conto dello stato attuale della legislazione, una legislazione in materia di integratori alimentari (vitamine, oligoelementi, ecc.) contribuirebbe a proteggere il consumatore senza limitarne la libertà d'accesso e di scelta e garantirebbe al terapeuta qualificato la libertà di prescrivere l'uso di tali prodotti,

Q. considerando la necessità, da un lato, di prevedere una fase transitoria che consenta a ciascun terapeuta oggi in attività di conformarsi alla nuova legislazione e, dall'altro, di istituire una commissione paritetica incaricata di esaminare, caso per caso, la situazione dei terapeuti in questione,

1. chiede alla Commissione, qualora i risultati dei relativi studi lo consentano, di impegnarsi in un processo di riconoscimento delle medicine non convenzionali e, a tal fine, di adottare le misure necessarie per favorire l'istituzione di comitati ad hoc;

2. chiede alla Commissione di realizzare prioritariamente uno studio approfondito per quanto concerne l'innocuità, l'efficacia, il campo di applicazione e il carattere integrativo o alternativo di ciascuna medicina non convenzionale, nonché uno studio comparativo dei sistemi giuridici nazionali esistenti cui sono soggetti coloro che praticano medicine non convenzionali;

3. chiede alla Commissione di stabilire, nella fase di elaborazione di una legislazione europea sulle varie forme di medicine non convenzionali, una netta distinzione tra medicine non convenzionali a carattere «integrativo» a le cosiddette medicine «alternative», vale a dire le medicine che si sostituiscono a quelle convenzionali;

4. invita il Consiglio a promuovere, dopo la conclusione dei lavori preliminari di cui al paragrafo 2 della presente risoluzione, programmi di ricerca nel settore delle medicine non convenzionali in cui si tenga conto dell'approccio individuale e olistico, del ruolo preventivo e delle specificità delle discipline mediche non convenzionali; si impegna, dal canto suo, a fare altrettanto;

5. chiede alla Commissione di riferire al più presto al Consiglio e al Parlamento sui risultati degli studi e delle ricerche già effettuati nel quadro della linea di bilancio B-7142 destinata sin dal 1994 alla ricerca sull'efficacia dell'omeopatia e di altre medicine non convenzionali;

6. chiede alla Commissione di vegliare, nell'ambito delle sue ricerche sull'efficacia delle terapie applicate nel quadro delle medicine non convenzionali, a che nessuna di tali pratiche terapeutiche, così come sono applicate negli Stati membri, faccia ricorso come rimedio curativo a organi di specie animali minacciate e sia pertanto coinvolta in un traffico illegale;

7. invita la Commissione a presentare un progetto di direttiva riguardante gli integratori alimentari, che spesso si collocano al confine tra prodotto dietetico e medicinale; tale legislazione dovrebbe consentire di garantire una valida prassi di fabbricazione ai fini della protezione del consumatore, senza per questo limitare la libertà di accesso o di scelta, garantendo a ogni terapeuta la

libertà di raccomandare tali prodotti; invita la Commissione a smantellare le barriere commerciali esistenti tra i vari Stati, accordando ai fabbricanti di prodotti per la salute la libertà di accedere a tutti i mercati dell'Unione;

8. incarica il suo Presidente di trasmettere la presente risoluzione al Consiglio, alla Commissione e ai governi degli Stati membri.

Successivamente il Parlamento Europeo deliberò la "**Risoluzione sulla relazione della Commissione al Parlamento europeo e al Consiglio sull'attuazione delle direttive 92/73/CEE e 92/74/CEE concernenti i medicinali omeopatici (COM (97) 0362 -C4-0484/97)"** di cui alla Gazzetta Ufficiale della Comunità Europea 23. 11. 98 IT C 359/11.

Con tale risoluzione il Parlamento europeo emanò la prima normativa comunitaria sui: riconoscimento, procedura specifica semplificata di registrazione, etichettatura e relative norme specifiche dei medicinali omeopatici.

LEGISLAZIONI NAZIONALI

REGNO UNITO DI GRAN BRETAGNA

A fronte di una certa diffusione in Gran Bretagna di pratiche terapeutiche riconducibili al novero delle "Medicine Non Convenzionali", precisi riferimenti normativi si rilevano nell'ordinamento inglese solo con riguardo ad alcune figure professionali operanti in ambito medico o di carattere complementare alla medicina tradizionale.

In particolare, il Professions Supplementary to Medicine Act 1960, a seguito di alcune successive integrazioni del testo originariamente approvato, disciplina attualmente l'esercizio di nove professioni "complementari alla medicina", fra le quali la "arts therapy" - particolare forma di psicoterapia che si avvale delle arti figurative a scopo terapeutico - risulta annoverata a fianco di altre più tradizionali professioni paramediche, quali il chiropodista/podologo (chiropodist/podiatrisf), il dietista (dietist), il tecnico di laboratorio clinico (medical laboratory scientist), l'occupational therapist (terapista della

riabilitazione funzionale/ergoterapeuta), l'ortottista (orthoptist), il fisioterapista (physiotherapist), il protesista/otoprotesista (prostehtist/orthotist) ed il tecnico radiologo (radiographist).

Due recenti leggi specifiche disciplinano inoltre l'esercizio della professione di osteopata (Osteopaths Act 1993) e di chiropratico (Chiropractors Act 1994).

La struttura organizzativa delineata dal Professions Supplementary to Medicine Act 1960 prevede l'istituzione di un "Consiglio per le professioni complementari alla medicina" (Council for Professions Supplementary to Medicine, CPSM) di livello nazionale ed una serie di specifici collegi professionali (boards), ciascuno competente per la professione paramedica di riferimento.

Al CPSM compete una funzione di coordinamento e supervisione delle attività dei singoli collegi professionali, secondo quanto specificato dall'articolo 1 della Legge:

a) formulando a ciascun collegio, o invitando ciascun collegio a formulare al Consiglio, proposte concernenti le attività da intraprendere a cura del singolo collegio o di altri collegi;

b) raccomandando ad un collegio di intraprendere tali attività, o di limitare le proprie attività secondo quanto il Consiglio ritenga idoneo, previa consultazione del collegio circa le suddette proposte;

c) occupandosi di questioni che appaiano di particolare interesse per due o più collegi, e fornendo ai collegi medesimi la consulenza ed assistenza che ritenga opportune riguardo a tali questioni;

d) esercitando i poteri ad esso attribuiti nel modo che il Consiglio stesso reputi più idoneo a garantire il proficuo esercizio delle funzioni e delle prestazioni di ciascun collegio ai sensi della legge in questione (Professions Supplementary to Medicine Act 1960, section 1 paragraph (3)).

L'articolo 2 della stessa legge assegna inoltre al Consiglio il compito di emanare, previa consultazione di tutti i collegi professionali, norme relative alla

forma, alla compilazione ed alla conservazione dell'apposito albo (Register) delle persone abilitate all'esercizio delle singole professioni.

Fra i compiti dei singoli ordini, oltre alla predisposizione, pubblicazione, aggiornamento e conservazione di tali albi (section 2, paragraphs (1), (4)) , l'articolo 4 (1) della legge indica anche l'approvazione, rispettivamente:

• dei corsi di formazione che il collegio ritenga idonei a conferire, alle persone che ne completino l'intera durata, le conoscenze teoriche e pratiche sufficienti per l'esercizio della professione di riferimento, e la definizione dei requisiti necessari ad esservi ammessi;

• dei titoli rilasciati ai candidati risultati idonei a seguito dell'esame conclusivo di un corso autorizzato, che abilitino, a giudizio del collegio, all'esercizio della professione di riferimento;

• degli istituti che il collegio ritenga conformemente organizzati ed attrezzati per condurre, in tutto o in parte, un corso di formazione approvato dal collegio. Rispetto a tali istituti è inoltre prevista una attività di supervisione da parte del collegio professionale competente, quanto al tipo di formazione impartita ed esami sostenuti presso ciascuno di essi (Professions Supplementary to Medicine Act 1960, section 5, paragraph (1)).

Nell'ambito di ciascun collegio, l'articolo 8 della Legge prevede inoltre l'istituzione di due apposite Commissioni, una di inchiesta ed una disciplinare (Investigating and Disciplinary Committees) investite, secondo il rispettivo ambito di competenza, della definizione dei casi in cui è prevista la cancellazione dall'Albo Professionale di persone iscritte, al ricorrere delle fattispecie espressamente indicate dal successivo articolo 9 della Legge:

• condanna penale per un reato che, ad avviso della commissione disciplinare istituita dal collegio, renda l'interessato inidoneo all'iscrizione all'albo;

• riconoscimento da parte della commissione disciplinare istituita dal collegio della condotta dell'interessato non conforme alla deontologia professionale;

• riconoscimento da parte della commissione disciplinare istituita dal collegio della iscrizione fraudolenta dell'interessato all'albo professionale.

Nei due Allegati (Schedules) alla Legge vengono infine riportate alcune disposizioni specifiche sul funzionamento del Consiglio e dei singoli collegi professionali fra cui in particolare la composizione dei rispettivi organi (21 membri per il Consiglio ed un numero di membri variabile da 11 a 21 per gli organi direttivi dei singoli collegi, First Schedule) e le norme relative alla costituzione e procedura delle commissioni disciplinari e di inchiesta (Second Schedule).

Due recenti leggi specifiche, di struttura sostanzialmente analoga, disciplinano invece, come si è detto, l'esercizio delle professioni di di osteopata e di chiropratico.

Ambedue infatti prevedono l'istituzione di un "Consiglio professionale generale" (General Osteopathic Council; General Chiropratic Council) articolato in quattro commissioni (c.d. Statutory Committees, rispettivamente per la formazione professionale, Education Committee; di inchiesta, Investigating Committee, per la condotta professionale, Professional Conduct Committee, e la commissione sanitaria, Health Committee per la valutazione dell'idoneità psico-fisica all'esercizio della professione) e di un apposito Albo Professionale - per cui è prevista la nomina da parte del Consiglio di un apposito "Conservatore dell'Albo" (Registrar of Osteopaths; Registrar of Chiropractors) - di cui si regolano le modalità di compilazione, pubblicazione e conservazione.

Una sezione specifica nel testo delle due leggi è dedicata agli standard di formazione professionale (Professional Education) rispetto ai quali la Education Committee svolge funzioni di promozione qualitativa ed ispezione mediante invio di propri incaricati nei singoli istituti di formazione.

Al pari delle altre professioni liberali, è inoltre prevista la predisposizione da parte del Consiglio di un apposito "Codice di Condotta" (Code of Practice)

rispetto al quale viene esercitata l'attività ispettiva e, se del caso, la funzione sanzionatoria da parte della Professional Conduct Committee o della Health Committee.

Contro le decisioni di tali organi, così come contro le decisioni del Conservatore dell'albo professionale ciascuna delle due leggi prevede un articolato sistema di ricorsi in appello, dapprima davanti ad organi interni (Consiglio generale; Appeal Tribunal istituito e procedente in base ad apposite norme stabilite dal Consiglio Generale) e quindi, secondo i casi, davanti alle competenti istanze ordinarie (High Court of Justice (Inghilterra e Galles); High Court of Justice (Irlanda del Nord); Court of Session (Scozia); "Sovrano in Consiglio" (Her Majesty in Council)).

In allegato a ciascuna delle due leggi sono riportate infine norme specifiche relative alla composizione ed al funzionamento ed del Consiglio e delle quattro Statutory Committees.

Con riguardo infine all'insieme delle numerose altre pratiche terapeutiche non convenzionali, un indice della loro diffusione in Gran Bretagna è rilevabile consultando via Internet (http://www.holistichealth.co.uk/direct.htm), fra i numerosi siti sull'argomento, un apposito elenco di tutte le specialità terapeutiche di tipo distico praticate nel Regno Unito (The United Kingdom Holistic Health Directory).

In alcuni casi, come ad esempio per l'omeopatia, si riscontra peraltro una consolidata tradizione che ha origine all'inizio del Novecento.

Sotto il profilo organizzativo, le principali Associazioni professionali che riuniscono le singole categorie di specialisti sono formalmente registrate (Registered Charities, quali ad es. la British Homoeopathic Association o la British Medical Acupuncture Society), o comunque costituite (ad es. la Association of Reflexologists), come "organizzazioni senza fini di lucro" (Charities) e come tali soggette alla relativa disciplina normativa.

Tali associazioni in particolare curano la promozione della formazione e dell'esperienza professionale nel settore specifico, organizzando o accreditando appositi corsi per l'apprendimento e lo sviluppo della conoscenza delle singole tecniche; emanano linee guida e codici di condotta circa i requisiti necessari all'esercizio della relativa terapia; provvedono alla diffusione dell'informazione al pubblico ed all'organizzazione e coordinamento a livello nazionale e/o regionale delle diverse attività settoriali, sia con proprie pubblicazioni sia attraverso i propri siti Internet.

Per quanto infine concerne l'immissione in commercio dei medicinali omeopatici, la Gran Bretagna ha recepito la direttiva 92/73/CEE del Consiglio con lo Statutory Instrument (SI) 1994/105, Medicines (Homoeopathic Medicinal Products for Human Use) Regulation 1994, successivamente modificato con SI 1994/899, SI 1994/2987 e SI 1996/482.

Con tale legislazione delegata sono state apportate modifiche alla legge che disciplina l'immissione in commercio dei prodotti farmaceutici (Medicines Act 1968), adeguandone i contenuti alla normativa comunitaria; in particolare il "certificato di registrazione" (Certificate of Registration) rilasciato in relazione ad un prodotto medicinale omeopatico è stato equiparato alla "licenza" (Product Licence) richiesta per l'immissione in commercio o l'esportazione dei prodotti farmaceutici ordinari (Medicines Act 1968, section 7, subsections 2(AJ). In mancanza di tale certificato risulta preclusa "qualunque attività corrispondente all'immissione sul mercato, nel senso specificato dalla Direttiva del Consiglio 92/73/CEE, del 22 settembre 1992" (Medicines Act 1968, section 7, subsections 2(B)).

Tutti i medicinali omeopatici sono rimborsabili su presentazione di ricetta mutualistica, che può essere rilasciata solo da medici con o senza specializzazione in omeopatia, sia in ambulatorio che in ospedale.

REPUBBLICA FEDERALE DI GERMANIA

La medicina alternativa, o non ufficiale, in Germania ha tradizioni consolidate ed è ampiamente diffusa, anche perché non è mai stata fortemente contrastata dalla medicina allopatica tradizionale. Molte delle cosiddette medicine alternative fra queste l'omeopatia e la medicina steineriana, sono infatti nate in area tedesca e qui all'inizio del '900 le pratiche naturaliste erano cosi diffuse che, a contenimento e a disciplina delle stesse, si rese necessario l'intervento del legislatore.

La figura del "curante pratico" o "guaritore" (l'intraducibile Heilpraktiker) è stata del resto riconosciuta fin dal 1939 con una "Legge sull'Esercizio Professionale della Scienza Medica senza decreto di nomina" (Gesetz uber die berufsmassige Ausulbung der Heilkunde ohne Bestallug), modificata solo in parte nel 1974 in tale norma la figura dell' Heilpraktiker è designata come colui che esercita, senza essere medico una pratica curativa capace di sanare o mitigare malattie, dolori o problemi fisici di qualsiasi natura (esclusa l'odontoiatria); il comma 3 specifica solo che e vietato l'esercizio nomade della professione. I requisiti richiesti si limitano al necessario possesso di un permesso che abilita all'esercizio delle pratiche curative; in assenza dello stesso, il trasgressore incorre in un'ammenda fino a 1500 DM.

Il primo regolamento attuativo della Legge (Erste Durchfilhrungsverordmmg zum Gesetz ùber die berufsmassige Ausubung der Heilkunde ohne Bestallung), sempre del 1939 regola invece nel dettaglio le premesse necessarie per l'ottenimento del permesso che si riducono all'aver compiuto il 25 anno di età, essere in possesso della cittadinanza-tedesca, aver portato a termine la scuola dell'obbligo, essere di comprovata rettitudine e moralità e, infine, risultare un esame dell'Ufficio d'igiene e sanità, idoneo all'esercizio per la salute pubblica.

In merito alla richiesta, come specificato nel comma 3 del regolamento, decidono le autorità amministrative inferiori d'intesa con l'ufficio d'igiene (...entscheidet die untore Verwaltungsbehórde im Benehmen mit dem

Gesundheitsamt). La risposta viene comunicata all'interessato e all'Ordine dei medici pertinente, e, qualora la domanda sia respinta deve essere accompagnata dai motivi del rifiuto. Il richiedente o l'ordine dei medici a cui questo appartiene possono presentare ricorso entro due settimane, il ricorso viene esaminato dalle autorità amministrative superiori dopo aver sentito un Comitato di esperti (Gutachterausschusses), formato da un presidente, che non deve essere ne un medico, ne un Heilpraktiker, da due medici e due Heilpraktikern. Essi vengono nominati dal Ministro degli Interni per un biennio.

Le richieste relative all'autorizzazione relativa all'apertura di uno studio di medicina (Antrage auf Zulassung zum Medizinstudium, comma 10) devono essere inoltrate alle autorità amministrative superiori del luogo di residenza del richiedente, che come unico requisito dovrà, oltre ad essere in possesso del permesso, non aver superato i 30 anni di età. Le autorità amministrative, dopo aver sentito il Comitato di esperti, decidono in merito alla domanda.

La definizione di "curatore pratico" contenuta nella legge non mira a stabilire quanto siano efficaci le cure praticate dall' Heilpraktiker, ma intende piuttosto dettare la compatibilità di tali metodi con la medicina tradizionale e li vieta solo nei casi in cui si dimostrino pericolosi per la salute pubblica. Tale impostazione diviene ancor più evidente nei richiami relativi alla figura professionale dell' Heilpraktiker contenuti in altre norme.

Nella "Legge sulla prevenzione e lotta delle malattie trasmissibili dell'uomo" (Gesetz zur Verhùtung und Bekampfung ubertragbarer Krankheiten beim Menschen) il comma 30 stabilisce, infatti, che le malattie infettive possono essere trattate solo da medici, e che i curatori pratici possono essere solo un tramite fra il malato infetto e il medico; mentre il regolamento sulla costituzione del comitato di esperti per l'autorizzazione dei medicinali, del comitato relativo agli obblighi dei farmacisti, nonché di quello relativo al controllo degli obblighi legati alla prescrizione dei medicinali (Verordnung zur

Errichtung von Sachverstàndigen-Auschussen furStandardzulassungen, Apothekenpflicht und Verschreibungspflicht von Arzneimittel), prevede in ciascun comitato la presenza di un curatore pratico, a testimoniare il pieno riconoscimento di tale figura nel panorama delle professioni sanitarie.

A conferma di quanto sopra, basti ricordare come le cure prestate dall' Heilpraktiker siano rimborsabili alla stessa stregua di quelle fornite da medici o dentisti, come risulta dal comma 3 del "Regolamento attuativo del comma 33 della legge sulla previdenza sociale degli impiegati pubblici" (Verordnung zur Diirchfùhrung des § 33 des Beamtenversorgungsgesetz).

Per ciò che riguarda più da vicino la medicina omeopatica, il suo iniziatore, Samuel Hahnemann, pubblicò i risultati dei suoi studi nel lontano 1796, e già nel 1829 venne fondata in Germania l'Associazione centrale tedesca dei medici omeopatici (Der Deutsche Zentralverein homóopatischer Àrtze), la più antica associazione di medici in terra tedesca, che oggi conta circa 3.200 iscritti. I medici omeopatici, dopo la laurea in medicina, sono tenuti a frequentare dei corsi post-universitari (che possono anche essere sostituiti da periodi di specializzazione presso cliniche od ospedali in cui si pratica la medicina omeopatica) riconosciuti a tal fine dall'Ordine dei medici federali.

Come risulta da un'indagine condotta dal Marplan-Institute, nel 1995 circa il 72% dei cittadini tedeschi faceva abitualmente uso di medicinali omeopatici, e tre medici su quattro li utilizzavano abitualmente per la cura di determinate patologie. I medicinali omeopatici, se prescritti da un medico, sono rimborsati dalle Casse Malattie; viceversa, non sono rimborsate le prestazioni dei medici omeopatici, se non in casi eccezionali quali ricoveri ed interventi d'urgenza.

REPUBBLICA FRANCESE

La Francia è il paese, assieme alla Germania e alla Gran Bretagna, dove le Medicine Non Convenzionali sono più sviluppate. Solo i laureati in medicina sono abilitati a praticare tali terapie.

In particolare l'omeopatia, l'osteopatia e la chiropratica sono molto diffuse ed esistono numerosi centri di insegnamento specializzati anche a livello universitario.

I medici omeopati sono più di ventimila. Sono stati istituiti degli appositi diplomi universitari, legalmente riconosciuti, denominati "Attestation d'Etude de Pharmacie Homéopathique".

Questi titoli vengono rilasciati dall'Università di Lione che è la più nota, di Lille e di Strasburgo.

Gli omeopati non medici ricevono la formazione in scuole private che non hanno alcun riconoscimento ufficiale.

Anche la professione di osteopata non è riconosciuta dalla medicina ufficiale.

Il Registre des Ostéopathes de France definisce le regole dell'etica e della deontologia professionale e rilascia il titolo di M.R.O.F. (Membre du Registre des Ostéopathes de France) per esercitare la professione.

La Collegiale Académique assicura la formazione secondo programmi definiti, organizza l'insegnamento e rilascia un diploma di osteopata necessario per divenire membro del R.O.F.

L'agopuntura è riconosciuta dal 1950 come metodo diagnostico e curativo riservato solo ai medici; anche la chiropratica è legalmente riconosciuta.

Nel Code de la Santè Publique non risulta annoverata la figura dell'omeopata o dell'osteopata tra le professioni mediche o medico ausiliarie (Parte IV), né sono menzionate altre figure professionali "non ufficiali".

Tuttavia tra i Médecins d'Exercice Particulier (MEP) è prevista la figura del medico specialista in omeopatia, in agopuntura e in idrologia (Circulaire DGR 8/5.2.1996 pour la mise à jour du fichìer des praticiens: qualification des

médecins spécialistes au regard de l'Assurance maladie (Arrété du ler juin 1994). Nouvelle liste des MEP).

REGNO DEL BELGIO

In Belgio l'uso delle medicine non convenzionali è stato regolamentato di recente con la Legge del 29 aprile 1999 *"Legge relativa alle pratiche non convenzionali nell'ambito della medicina, della farmacia, della kinesiterapia, dell'attività infermieristica e delle professioni paramediche"* (Loi relative aux pratiques non conventionnelles dans les domaines de l'art medical, de l'art pharmaceutique, de la kinésithérapie, de l'art infîrmier et des professions paramédicales) e con il Decreto Reale attuativo del 4 luglio 2001, relativo al riconoscimento delle organizzazioni professionali di coloro che esercitano una pratica non convenzionale o ritenuta tale nell'ambito della medicina.

Nella citata legge vengono definite come pratiche non convenzionali quelle terapie che mirano a migliorare e preservare lo stato di salute dei pazienti e vengono dettate le regole e le condizioni secondo cui debbono essere esercitate.

Sono ritenute pratiche mediche non convenzionali: l'omeopatia, la chiropratica, l'osteopatia e l'agopuntura; altre pratiche che hanno ottenuto riconoscimento ufficiale dal re tramite istituzione di un'apposita "Camera".

Le organizzazioni professionali dei praticanti di tali terapie per ottenere e mantenere il relativo riconoscimento debbono soddisfare le seguenti condizioni (decreto 4.7.2001): essere riconosciute come unioni professionali conformemente alla legge del 31 marzo 1898 sulle Unioni professionali; indirizzarsi a coloro che esercitano queste attività almeno in due delle tre regioni in cui, secondo l'art. 3 della Costituzione, si divide lo Stato Belga (vallone, fiamminga e tedesca); disporre di un regolamento interno che regola i diritti e i doveri dei suoi membri; stabilire norme concernenti i compensi economici relativi all'esercizio della pratica; stabilire norme relative all'iscrizione di nuovi membri soprattutto per quanto riguarda la formazione di base e specifica, gli stages pratici effettuati, i diplomi o certificati posseduti,

l'istituto che li ha rilasciati, la formazione permanente e la valutazione delle qualità; avere la copertura delle responsabilità civili e professionali di tutti i suoi membri presso un'impresa di assicurazione legalmente autorizzata e riconosciuta in Belgio; impegnarsi a partecipare alla ricerca scientifica; rendere pubbliche le terapie mediche utilizzate, i progressi scientifici e i risultati raggiunti nella cura dei pazienti; impegnarsi ad inviare annualmente al Ministro della sanità la lista dei membri dell'organizzazione con i relativi diplomi, certificati e gli indirizzi dove essi esercitano la professione.

Il riconoscimento dell'organizzazione professionale viene accordato per un periodo di sei anni e può essere rinnovato.

Un'apposita Camera "Chambre" è stata istituita per ciascuna delle pratiche non convenzionali: omeopatia, chiropratica, osteopatia, e agopuntura e per le altre riconosciute dal Re di sua iniziativa o a seguito di domanda inoltrata dalle relative organizzazioni professionali.

Ciascuna Camera comprende cinque mèmbri proposti dalle facoltà di medicina e altri cinque nominati tra coloro che esercitano la pratica non convenzionale relativa alla Camera in questione.

Una Commissione paritaria "Commission Paritarie" per le medicine non convenzionali è stata istituita dal Ministro della Sanità: essa è composta per metà da membri proposti dalle facoltà di medicina e per l'altra metà da membri proposti dalle camere delle discipline non convenzionali.

La Commissione ha il compito di esprimere il proprio parere, sulla base della proposta di parere formulata da una delle Camere, e trasmetterlo al ministro della Sanità.

I pareri della Commissione Paritaria riguardano le condizioni generali applicabili all'esercizio di tutte le pratiche non convenzionali riconosciute, in particolar modo l'assicurazione professionale, la copertura minima, l'appartenenza ad una organizzazione professionale riconosciuta, un sistema di

registrazione e di pubblicità, la lista degli atti non autorizzati per i praticanti non medici.

La Commissione si esprime anche sull'opportunità di registrazione delle pratiche non convenzionali tenendo conto di criteri fondamentali quali la qualità delle cure, la loro accessibilità e la loro influenza positiva sullo stato di salute dei pazienti (art.3).

Non è possibile esercitare una pratica non convenzionale riconosciuta se non dopo aver ottenuto la relativa registrazione individuale. Questa viene accordata dal Ministro della Sanità, su parere della Camera competente, se il richiedente ottempera alle condizioni fissate dall'articolo 3 della presente legge. La Camera, comunque, non può emettere parere negativo prima di aver dato all'interessato il diritto di replica (art. 8).

Un aspetto importante della legge riguarda l'obbligo di informazione.

Tutti i praticanti di terapie non convenzionali registrati debbono avere un dossier per ciascun paziente: prima di iniziare un trattamento coloro che non sono in possesso di laurea in medicina, sono tenuti a chiedere al paziente di portare una diagnosi recente relativa alla suo stato di salute redatta da un medico di sua scelta, se il paziente non acconsente a consultare un medico prima del trattamento deve esprimere la sua volontà per iscritto (art. 9).

Coloro che praticano terapie non convenzionali debbono prendere tutte le precauzioni per evitare che i propri pazienti siano privati dei trattamenti convenzionali.

A tal fine sono tenuti ad informare un medico, a sua richiesta, dell'evoluzione dello stato di salute del paziente.

Per quanto riguarda le disposizioni penali la legge prevede: detenzione da otto giorni a sei mesi e ammenda da cinquecento a cinquemila franchi per coloro che esercitano terapie non convenzionali senza avere la relativa registrazione; ammenda da duecento a cinquemila franchi per chi, non titolare di laurea in

medicina, abbia eseguito trattamenti senza preventiva diagnosi stabilita da un medico, come previsto dall'articolo 9.

REGNO DEI PAESI BASSI

Una innovazione significativa e forse degna di studio approfondito per la sua applicabilità in Italia invece, viene dall'Olanda con una legge approvata il 9 novembre 1993, la "Legge per la Riforma delle Professioni della Salute".

Ritengo utile riportare la legge olandese qui in modo più dettagliato, perché con essa viene introdotto un nuovo concetto e viene infatti percorsa una strada che al contempo assicura la qualità delle prestazioni sanitarie, tutela la salute e l'incolumità del cittadino malato e permette la più ampia scelta in materia di metodologie di cura.

La nuova legge olandese è una legge quadro da essere completata con decreti specifici e sostituisce tutte e dodici le norme legislative preesistenti sulle professioni sanitarie.

La nuova norma fa un passo significativo nell'abbandonare il vecchio divieto dell'esercizio della "professione medica" senza autorizzazione, aprendo così il campo delle cure e della salute a tutti, specialmente a tutte le professionalità che sono cresciute nel campo della medicina alternativa All'utente viene data la possibilità di scegliere liberamente, a quale terapeuta rivolgersi.

Per prevenire, dall'altro canto, rischi inaccettabili per la salute derivanti da incompetenza professionale, certe procedure vengono escluse in modo specifico, cioè vengono riservate a determinate figure professionali, inoltre viene introdotto il divieto di agire in modo da arrecare danni alla salute di una persona.

Citiamo gli aspetti principali della nuova legge olandese:

1) Qualità: La legge crea le precondizioni per lo sviluppo e il monitoraggio di standard di qualità nella sanità individuale. Se necessario, si potrà intervenire con decreti per dare altre regole a certi aspetti qualitativi come l'aggiornamento professionale, ecc.

2) Protezione dei titoli: La scomparsa del divieto dell'esercizio della professione medica senza autorizzazione significa la fine del sistema delle professioni protette. L'esercizio delle funzioni mediche non è più ristretto a certi professionisti medici. La nuova legge introduce un sistema di protezione dei titoli di un numero limitato di professioni. La protezione dei titoli può avvenire per legge o per decreto

ministeriale. La differenza principale è che l'albo delle professioni solo nel primo caso viene istituito e mantenuto dal governo. La legge stessa individua otto professioni a titolo protetto che hanno dei regolamenti per quanto riguarda i corsi di studio e le competenze professionali. Le funzioni ristrette (vedi sotto) ricadono in una o nell'altra di queste otto professioni.

Si tratta delle seguenti professioni: medico; dentista; chimico farmaceutico; psicologo clinico; psicoterapeuta; fisioterapeuta; ostetrica; infermiera;

3) Registrazione: Sono stati istituiti registri ufficiali per quelle otto professioni. Può esercitare solamente chi è iscritto nel relativo registro. La registrazione non è automatica. Necessita di domanda e del pagamento di una tassa. E' previsto anche un limite temporale dell'iscrizione con la necessità di ripresentare la domanda e una conseguente valutazione della competenza professionale. Il registro è aperto al pubblico, cioè può essere ispezionato sia dalla persona stessa che dal pubblico in generale.

La registrazione delle altre professioni è volontaria ed è previsto che sia applicata soprattutto a professioni paramediche, come per esempio logopedista, igienista dentale e dietologa. I decreti applicabili a quel tipo di professione detteranno regole di studio e daranno una definizione dell'area di competenza. La legislazione proteggerà l'uso del relativo titolo. Il governo non istituirà però un registro, che potrà invece essere istituito dalle società professionali.

4) Specializzazioni: Nel corso degli anni si sono sviluppate delle specializzazioni che non avevano finora delle regole individuali. La nuova

legge permette di dare dei regolamenti a queste specializzazioni, proteggendone il titolo ed assicurando la competenza degli operatori.

5) Le procedure riservate: II principio di base della nuova legislazione è che l'esercizio della medicina è aperto a tutti. Ma la legge fa certe eccezioni a questa regola. Alcune procedure possono essere messe in atto solo da professionisti autorizzati per legge. Queste sono le procedure che comportano un alto grado di rischio per il paziente se utilizzate da persone non esperte. E' un fatto penale l'utilizzo di queste procedure senza la dovuta autorizzazione. Si tratta di: procedure chirurgiche; procedure ostetriche; utilizzo di cateteri ed endoscopie; punture ed iniezioni; anestesia generale; procedure che richiedono l'impiego di sostanze radioattive e delle radiazioni ionizzanti; cardioversione; defibrillazione; terapia elettroconvulsiva; litotripsia; inseminazione artificiale.

Le procedure riservate possono essere utilizzate da due gruppi di persone: quelle che hanno l'autorizzazione diretta e quelle che possono utilizzare una procedura su ordine di un professionista autorizzato. Autorizzazione diretta è data dalla legge ai medici, ai dentisti ed alle ostetriche, specificando per ogni professione quali sono le procedure ammesse. Sono state stabilite anche delle regole sotto le quali un professionista non autorizzato può utilizzare delle procedure ristrette, su ordine sempre di un professionista autorizzato.

6) Codice Disciplinare: Le professioni regolamentate per legge avranno un loro codice disciplinare; le leggi civili e penali non contengono strumenti adatti a questo scopo. La revisione dei vecchi codici disciplinari è diretta verso una maggiore apertura al pubblico delle procedure. Le misure disciplinari vanno dal semplice avvertimento alla radiazione del nominativo dal registro. Le persone radiate per ragioni disciplinari non possono essere riammesse.

REGNO DI SPAGNA

In Spagna non vi sono disposizioni legislative nazionali sulle professioni mediche alternative o non convenzionali.

La legislazione vigente è relativa solamente ai farmaci omeopatici ed è stata dettata in attuazione di due direttive comunitarie.

Le disposizioni alle quali si è accennato sono costituite da due regolamenti, ovvero il Real Decreto 2208 del 16/11/1994, riguardante i medicamenti omeopatici destinati all'uomo ed il Real Decreto 110 del 27/1/1995, relativo ai medicamenti omeopatici di uso veterinario.

Il decreto 2208/1994 recepisce la direttiva comunitaria 92/73 e precisa i requisiti necessari a garantire l'osservanza di criteri di qualità e sicurezza nelle diverse fasi di trattamento del prodotto (autorizzazione, produzione, controllo, pubblicità e vendita). Come prefigurato dalla direttiva CEE sono possibili due modalità di autorizzazione: con o senza indicazione terapeutica approvata. La seconda consiste in una procedura semplificata di registrazione, attuabile nelle seguenti circostanze: via di somministrazione orale od esterna; assenza di indicazioni terapeutiche particolari sull'etichetta od in qualunque informazione relativa al farmaco; grado di diluizione tale da garantire l'innocuità del prodotto ovvero non più di una parte su diecimila di tintura madre ne più della centesima parte della più piccola dose eventualmente usata nella medicina allopatica, in riferimento a quei principi attivi la cui presenza in un farmaco allopatico comporti l'obbligo della ricetta medica.

Va sottolineata l'esclusione dei tarmaci omeopatici dalle prestazioni previste dal servizio sanitario nazionale spagnolo (Sistema Nacional de Salud) e da ogni forma di finanziamento con fondi afferenti al sistema della sicurezza sociale (Seguridad Social).

Il decreto 110/1995 attua invece la direttiva 92/74 ed intende sottomettere i farmaci omeopatici per animali al regime generale esistente per i medicamenti veterinari. Anche per i prodotti omeopatici veterinari è possibile una

procedura semplificata di registrazione, prevista nei seguenti casi: somministrazione ad animali di compagnia od a specie esotiche la cui carne o i prodotti dei quali non siano destinati al consumo umano; via di somministrazione descritta dalla Real Farmacopea Espanda, dalla Farmacopea europea o, in loro assenza, da una delle farmacopee ufficiali usate nei paesi dell'Unione Europea; assenza di indicazioni terapeutiche particolari sull'etichetta od in qualunque informazione relativa al farmaco; grado di diluizione tale da garantire l'innocuità del prodotto ovvero non più di una parte su diecimila di tintura madre ne più della centesima parte della più piccola dose eventualmente usata nella medicina allopatica, in riferimento a quei principi attivi la cui presenza in un farmaco allopatico comporti l'obbligo della ricetta medica.

REPUBBLICA DEL PORTOGALLO

Nel mese di ottobre 2001 è ripreso, all'Assemblea della Repubblica Portoghese, l'esame dei progetti di legge n. 34 e n. 320 sulle Medicine Non Convenzionali.

Particolare rilevanza assume il progetto n. 320, presentato dal gruppo parlamentare socialista, che ha la maggioranza dei deputati nell'Assemblea della Repubblica. L'art, 3, comma 1, del progetto rinvia, per quanto riguarda la definizione di "medicine non convenzionali", a quanto stabilito, in via generale, dall'Organizzazione Mondiale della Sanità, cioè a quelle pratiche mediche che si basano su "Una base filosofica differente dalla medicina convenzionale", con conseguente applicazione di metodi terapeutici diversi. Li particolare sono esplicitamente menzionate, al comma 2: agopuntura, omeopatia, osteopatia, chiropratica e fitoterapia.

L'art 4 elenca sei principi orientativi comuni nella pratica della medicina non convenzionale:diritto individuale di scelta del metodo terapeutico; rispetto del diritto dell'individuo alla tutela della salute; esercizio delle pratiche mediche alternative ad un elevato grado di responsabilità, diligenza e competenza; possibile attuazione di pratiche mediche convenzionali e non convenzionali in

forma alternativa o complementare, nel rispetto della volontà del paziente; promozione della ricerca scientifica nelle diverse aree della medicina non tradizionale, al fine di ottenere dei modelli di qualità ed efficacia; autonomia tecnica e deontologica nell'esercizio delle medicine non convenzionali, nel rispetto dell'etica e delle buone pratiche professionali.

Per quanto riguarda la definizione dello status professionale dei medici non convenzionali, il progetto propone l'istituzione di una commissione tecnica (art. 8), dipendente dal Ministero della Sanità (Ministerio da Saùde), con lo scopo di studiare e proporre degli standard per la formazione, il riconoscimento e la certificazione dei professionisti che operano nell'ambito della medicina non tradizionale.

La commissione è composta da (art. 9): tre rappresentanti del Ministero della Sanità, uno dei quali la presiede; due rappresentanti del Ministero dell'Istruzione; un rappresentante dell'Ordine dei Medici; un rappresentante per ciascuna delle cinque pratiche mediche non convenzionali, citate all'art. 3.

L'esercizio delle pratiche mediche alternative spetta quindi solo ai professionisti in possesso dei titoli legalmente riconosciuti, I medici sono obbligati a tenere un registro con i dati ed i procedimenti relativi a ciascun paziente ed operano sotto il principio generale della responsabilità individuale (art. 11). Nei locali dove operano i medici deve essere affissa la documentazione relativa alla loro certificazione professionale (art. 12).

Tutti i prodotti e gli strumenti utilizzati devono obbedire ai requisiti di qualità e sicurezza stabiliti dalla normativa generale sulla tutela della salute. Tutti i farmaci e gli altri preparati, usati nei diversi ambiti della medicina non tradizionale, devono recare informazioni in lingua portoghese, relative alle loro caratteristiche e alle precauzioni per l'uso (art. 13).

Per quanto riguarda gli utenti delle pratiche mediche complementari, si applicano anche ad essi i principi generali della libertà di scelta, del consenso informato e del diritto all'informazione. Tutti i dati e le notizie relative ai

pazienti, in possesso dei medici, sono soggette a riservatezza. Gli utenti delle pratiche mediche alternative, al fine di salvaguardare i propri interessi, possono presentare eventuali denunce presso gli organismi competenti del Ministero della Sanità (art. 15-18).

La parte finale del progetto contiene disposizioni relative alle possibili infrazioni ed alle corrispondenti sanzioni, che sono tutte di natura pecuniaria (art. 20- 22); ad esse si aggiungono, come sanzioni accessorie, il sequestro dei prodotti e degli strumenti usati e l'interdizione, temporanea o definitiva, dall'esercizio dell'attività professionale (art. 23).

Nel progetto n. 34 del blocco della sinistra sono invece definite come "medicine non convenzionali" tutte quelle che operano "in forma complementare o alternativa" alle medicine fino ad ora legalmente riconosciute e che utilizzano "strumenti o agenti bioterapeutici" (art. 1).

L'art. 2 proclama sia il principio della libera scelta, da parte dei cittadini, del metodo terapeutico desiderato sia il diritto, da parte dei medici non convenzionali, ad esercitare la propria professione, purché debitamente certificata e qualificata.

Dato che è proprio la qualificazione e lo status professionale dei medici, a partire dagli studi effettuati, che garantisce la qualità del trattamento riservato ai pazienti, anche qui si propone l'istituzione di una Commissione Nazionale di Periti composta da due professionisti e ricercatori per ciascuna delle aree della medicina non tradizionale, due rappresentanti della medicina convenzionale, due del Ministero della Sanità (Ministério da Saùde) e due del Ministero dell'Istruzione (Ministério da Educacao).

Alla commissione sono assegnati i seguenti compiti (art. 5): seguire il processo di legalizzazione degli istituti di insegnamento e di formazione professionale riguardanti le medicine non convenzionali, raccogliere le informazioni e la legislazione relativi ai corsi esistenti all'estero; raccogliere informazioni sui lavori di studio e di valutazione dell'efficacia di queste pratiche mediche;

procedere alla divulgazione di queste informazioni assieme agli interessati; elaborare una lista delle terapie di efficacia riconosciuta, a livello internazionale; procedere alla certificazione, in una fase transitoria, dei professionisti che agiscono nell'ambito delle medicine non convenzionali.

Per quanto riguarda farmaci e prodotti omeopatici è proposto il loro inserimento negli schemi normali di compartecipazione alla spesa, previsti dal Servizio Sanitario Nazionale (Servico Nacional de Saùde), mentre per tutti gli altri prodotti è comunque prevista la possibilità di prescrizione medica, da parte dei rispettivi professionisti (art. 7).

Anche in relazione alle cure mediche, nel momento in cui un trattamento terapeutico è riconosciuto come efficace ed entra a far parte della lista sopra menzionata, deve essere prevista la compartecipazione pubblica alla spesa sostenuta come avviene per la medicina convenzionale, nonché la sottoscrizione di convenzioni con il Servizio Sanitario nazionale (art. 8).

Negli ambulatori e negli altri locali dove si prestano cure di medicina non tradizionale deve essere esposta la documentazione relativa alla certificazione professionale dei medici responsabili. Il rilascio dell'autorizzazione all'apertura spetta alla Direziono Generale Sanitaria del Ministero della Sanità, attraverso le diverse amministrazioni sanitarie regionali, entro 30 giorni dalla richiesta e dopo aver valutato l'adeguata qualificazione del personale e verificato le condizioni di sicurezza, igiene e salubrità della sistemazione (art. 9).

REPUBBLICA ITALIANA

La Costituzione della Repubblica all'art. 117 (art. 3 Legge Costituzionale 18/10 n. 3), l'art. 6, comma 3, del d.lgs. 30/12/99 n. 502 (sub art. 7 d. lgs. N. 517 del 7/12/1993) e l'art. 1, comma 2, Legge n. 42 del 26/02/1999 riservano esplicitamente allo Stato l'individuazione delle figure professionali di pratiche terapeutiche non convenzionali, ancorché sia stato modificato il Titolo V della Costituzione (Legge Costituzionale 3/2001).

Un riconoscimento indiretto delle Medicine Non Convenzionali si ritrova nei: Decreto del Ministero della Salute del 22.07.96 che include l'agopuntura ed altre terapie tra le prestazioni di assistenza specialistica ambulatoriale erogabili nell'ambito del Servizio Sanitario Nazionale; Decreto del Presidente della Repubblica n. 271 del 2000 che include l'agopuntura tra le prestazioni aggiuntive svolte dallo specialista in regime di attività extramoenia; il Decreto del Presidente del Consiglio del 29.02.2001, provvedimento di definizione dei livelli essenziali di assistenza (LEA), che fa espresso riferimento alle Medicine Non Convenzionali e le include tra le terapie a totale carico dell'assistito.

Una disciplina dei medicinali omeopatici è stata introdotta col Decreto Legislativo n. 185 del 1995, in attuazione della Direttiva della Comunità Europea n. 73 del 1992.

Per quanto riguarda gli aspetti fiscali, la Legge n. 342 del 2000 ha ridotto l'aliquota IVA sui medicinali omeopatici, portandola dal 20% al 10%, allineandola a quella prevista per i farmaci convenzionali..

Nella XIII legislatura si era giunti ad un testo base con l'accordo di tutte le forze politiche, non approvato a causa della fine della legislatura.

All'inizio della XIV legislatura venne riproposto il tema delle Medicine Non Convenzionali alla Commissione Affari Sociali col Progetto di Legge n. 1103 in 13 articoli.

Il 18 maggio 2002 il Consiglio Nazionale della FNOMCeO ha emanato le "Linee guida sulle Medicine e Pratiche Non Convenzionali".

Per l'importanza che tale deliberazione ha, ritengo opportuno riportarne integralmente il contenuto:

Il Consiglio Nazionale della FNOMCeO, riunito a Terni il 18 maggio 2002,

Vista la decisione del Comitato Centrale del 3 maggio 2002 in materia di medicine e pratiche non convenzionali che ha fatto proprie le risultanze dei lavori della Commissione per l'esame della problematiche rivenienti dalla medicina non convenzionale nominata dal Comitato Centrale in data 26 settembre 2001;

Vista la risoluzione n. 75 del Parlamento europeo del 29 maggio 1997 e la risoluzione n. 1206 del Consiglio d'Europa del 4 novembre 1999, sullo stato delle medicine non convenzionali, nelle quali viene constatata la crescente diffusione delle stesse e ribadita la necessità di assicurare ai cittadini il più elevato livello di sicurezza e l'informazione più corretta;

Vista la carenza di interventi chiarificatori da parte di altre Autorità competenti a normare la materia, più volte sollecitato a pronunciarsi dalla Federazione;

Vista l'entità del fenomeno che secondo le ultime stime ISTAT (1999-2000) è in rapido incremento nelle società industrializzate;

Vista la forte aspettativa di interventi di garanzia da parte della pubblica opinione;

Preso atto della mutata concezione del "bene salute" che l'Organizzazione Mondiale della Sanità definisce come stato di benessere fisico, psichico e sociale, complessivo, e non solo come assenza di malattia;

Consapevole della necessità che il medico, nell'esplicazione della propria attività professionale si ponga, oggi, di fronte ad un'immagine dell'uomo che tenga conto di tutti gli aspetti anche non riconducibili a schemi predefinibili relativi a salute e malattia;

Considerata la necessità di una più attenta valutazione dei possibili e diversi approcci diagnostici e terapeutici finalizzati a garantire ai cittadini la più ampia libertà possibile di scelta terapeutica;

Valutata l'opportunità, nell'attuale contesto socio culturale, sulla base del consenso libero ed informato, di valorizzare un sistema di conoscenze, quali le medicine e le pratiche non convenzionali, che non si ponga in antitesi ai principi irrinunciabili fondanti della Medicina Ufficiale;

Ravvisata l'opportunità di integrazione delle medicine e pratiche non convenzionali di cui può beneficiare il cittadino;

Considerata la ferma intenzione della Federazione nazionale dei medici chirurghi e degli odontoiatri di rinsaldare il proprio ruolo istituzionale di primo garante della professione presso i cittadini e presso lo Stato, a tutela della collettività;

Visto l'assunto, ribadito anche da numerose pronunce giurisprudenziali, che quanto attiene alla diagnosi e alla cura delle malattie ovvero l'atto medico deve avere un'adeguata garanzia nel superiore interesse della salute e che tale garanzia è data dalle conoscenze e dalla competenza di chi esercita attività rivolta alla tutela della salute; condizioni che lo Stato controlla attraverso l'iter degli studi universitari, la laurea, l'abilitazione post laurea, nonché l'iscrizione all'albo tenuto dall'Ordine professionale;

Ribadito il principio che il medico pur nella piena libertà di scelta terapeutica dovrà, comunque in scienza e coscienza, attenersi alle regole della prudenza e che, nel rispetto delle conoscenze scientifiche è tenuto a far sì che il cittadino, adeguatamente informato, non si sottragga a specifici trattamenti di comprovata efficacia;

DELIBERA

Di approvare il documento allegato contenente le linee guida della FNOMCeO su medicine e pratiche non convenzionali.

LE LINEE GUIDA DELLA FNOMCeO SULLE MEDICINE E PRATICHE NON CONVENZIONALI

Le medicine e le pratiche non convenzionali ritenute in Italia come rilevanti da un punto di vista sociale sia sulla base delle indicazioni della Risoluzione n. 75 del Parlamento Europeo del 29/5/97 e della Risoluzione n. 1206 del Consiglio d'Europa del 4/11/99 che sulla base della maggiore frequenza di ricorso ad alcune di esse da parte dei cittadini oltre che degli indirizzi medici non convenzionali affermatisi in Europa, negli ultimi decenni, sono:

Agopuntura

Fitoterapia

Medicina Ayurvedica

Medicina Antroposofica

Medicina Omeopatica

Medicina Tradizionale cinese

Omotossicologia

Osteopatia

Chiropratica

L'esercizio delle suddette medicine e pratiche non convenzionali è da ritenersi a tutti gli effetti atto medico e pertanto si ritiene:

essere le medicine esercitabili e le pratiche gestibili, in quanto atto medico, esclusivamente da parte del medico chirurgo ed odontoiatra in pazienti suscettibili di trarne vantaggio dopo un'adeguata informazione e l'acquisizione di esplicito consenso consapevole;

essere il medico chirurgo e l'odontoiatra gli unici attori sanitari in grado di individuare pazienti suscettibili di un beneficiale ricorso a queste medicine e pratiche, in quanto solo il medico chirurgo e l'odontoiatra sono abilitati all'atto diagnostico, che consente la corretta discriminante fra utilità e vantaggio del ricorso consapevole a trattamenti non convenzionali;

essere, in questa impostazione, il medico chirurgo e l'odontoiatra gli unici in grado di evitare che le medicine e pratiche non convenzionali vengano proposte e prescritte a pazienti senza possibilità di vantaggio, sottraendoli alle disponibili terapie scientificamente accreditate sulle quali dovrà essere sempre aggiornato attraverso l'ECM;

essere il medico chirurgo e l'odontoiatra gli unici soggetti legittimati ad effettuare diagnosi, e a predisporre il relativo piano terapeutico e a verificare l'attuazione dello stesso sul paziente;

essere dovere della FNOMCeO e di tutti gli Ordini provinciali, perseguire nei modi dovuti e con tempestività, denunciando all'autorità competente chiunque, non medico, eserciti le suddette medicine e pratiche non convenzionali;

essere dovere della FNOMCeO e di tutti gli Ordini provinciali perseguire disciplinarmente quei medici chirurghi e odontoiatri che non rispettino, a norma del vigente Codice Deontologico, le regole sopra richiamate o che svolgano attività di prestanomismo a copertura di prestazioni da parte di non medici relativamente alle medicine e pratiche non convenzionali sopra elencate;

essere opportuna la costituzione a livello nazionale FNOMCeO di una banca dati sulla legislazione internazionale, nazionale e regionale dedicata alle medicine e pratiche non convenzionali anche su segnalazione dei singoli Ordini provinciali;

di richiedere con forza, per far corrispondere alla consistente domanda di medicine e pratiche non convenzionali, un coerente sviluppo di sistemi preposti alla tutela dell'efficacia e sicurezza, la costituzione di un'Agenzia nazionale composta da soggetti istituzionali quali: il Ministero della Salute, le Regioni, il MURST, e la FNOMCeO.

Tra i compiti principali da affidare a tale Organismo, che potrebbe articolarsi in analoghe strutture regionali, sono da prevedersi:

l'individuazione e la regolamentazione delle attività relative alle singole medicine e pratiche non convenzionali;

le promozione della ricerca di base e applicata, secondo le regole di buona pratica clinica, nelle aree esclusive e soprattutto in quelle integrate favorendo la conoscenza dei princìpi e dell'uso appropriato delle medicine e pratiche non convenzionali nella cultura medica, avvalendosi di finanziamenti propri e derivanti da soggetti pubblici e privati in ambito nazionale ed europeo;

il monitoraggio e l'informazione, attraverso relazioni semestrali/annuali alle istituzioni responsabili della tutela della salute, sull'uso appropriato, efficace e sicuro delle medicine e pratiche non convenzionali;

la regolamentazione dei percorsi formativi attraverso:

l'individuazione dei criteri per l'adozione degli ordinamenti didattici;

la definizione dei criteri e dei requisiti per l'accreditamento dei soggetti pubblici e privati coinvolti nelle attività di formazione;

la sollecitazione, alle istituzioni competenti, a predisporre tutti quei provvedimenti di carattere normativo o regolamentare utili al perseguimento dei propri scopi istitutivi;

sollecitare il Parlamento ad attivarsi affinché si pervenga ad una modifica normativa sulla pubblicità sanitaria su proposta della FNOMCeO con l'inserimento di norme specifiche per il settore;

sollecitare le Autorità competenti ad attivarsi al fine dell'inserimento delle voci, relative alle prestazioni professionali rese nell'esercizio delle medicine e pratiche non convenzionali sopra elencate, all'interno della Tariffa minima nazionale degli onorari per le prestazioni medico chirurgiche ed odontoiatriche (DPR 17/2/1992), che, peraltro, necessita di una sostanziale e globale revisione;

prevedere l'istituzione presso gli Ordini provinciali dei Medici chirurghi e degli Odontoiatri di un registro suddiviso in sezioni per ciascuna delle medicine e pratiche non convenzionali sopra elencate. L'inserimento nel

registro dei medici chirurghi e degli odontoiatri è subordinato alla individuazione di criteri che verranno stabiliti con atto di indirizzo e coordinamento della FNOMCeO, in collaborazione con le Scuole e Società Scientifiche accreditate dalla FNOMCeO stessa, nella distinzione di ruoli e funzioni.

La Federazione Nazionale dei Medici Chirurghi e degli Odontoiatri

CHIEDE

con forza urgente e indifferibile intervento legislativo del Parlamento, al fine dell'approvazione di una normativa specifica concernente le medicine non convenzionali sulla base di quanto contenuto nel presente documento.

ATTIVITA' PARLAMENTARE INTERNAZIONALE

Ritengo che a livello europeo il documento parlamentare più completo, strategicamente determinante ed esemplare per la rigorosa, affidabile, scrupolosa e imparziale metodologia e conduzione dei lavori svolti sia il **"Sixth Report"** del "*Select Committe on Science and Technology of House of Lords"* (The United Kingdom Parliament, House of Lords, Select Committee appointed to consider Science and Technology, Sixth Report, Report on Complementary and Alternative Medicine, 21st November 2000) di cui riporto il:

SUMMARY OF RECOMMENDATIONS

Many of our recommendations make reference to the way we have organised therapies into three separate groups in the Report. These groupings are outlined in detail in Chapter 2 but for ease of reference a short synopsis of our grouping system is as follows:

The first group embraces what may be called the principal disciplines, two of which, osteopathy and chiropractic, are already regulated in their professional activity and education by Acts of Parliament. The others are acupuncture, herbal medicine and homeopathy. Each of these therapies claims to have an individual diagnostic approach and are seen as the 'Big 5' by most of the CAM world.

The second group contains therapies which are most often used to complement conventional medicine and do not purport to embrace diagnostic skills. It includes aromatherapy; the Alexander Technique; body work therapies, including massage; counselling, stress therapy; hypnotherapy; reflexology and probably shiatsu, meditation and healing.

The third group embraces those other disciplines which purport to offer diagnostic information as well as treatment and which, in general, favour a philosophical approach and are indifferent to the scientific principles of conventional medicine, and through which various and disparate frameworks of disease causation and its management are proposed. These therapies can be

split into two sub-groups: Group 3a includes long-established and traditional systems of healthcare such as Ayurvedic medicine and Traditional Chinese medicine. Group 3b covers other alternative disciplines which lack any credible evidence base such as crystal therapy, iridology, radionics, dowsing and kinesiology.

Introduction (Chapter 1)

2. More detailed quantitative information is required on the levels of CAM use in the United Kingdom, in order to inform the public and healthcare policy-makers, and we recommend that suitable national studies be commissioned to obtain this information (para 1.21).

Evidence (Chapter 4)

3. Diagnostic procedures must be reliable and reproducible and more attention must be paid to whether CAM diagnostic procedures, as well as CAM therapies, have been scientifically validated. We agree that this is an issue that should always be kept in mind when doing research in this area (para 4.16).

4. In our opinion any therapy that makes specific claims for being able to treat specific conditions should have evidence of being able to do this above and beyond the placebo effect. This is especially true for therapies which aim to be available on the NHS and aim to operate as an alternative to conventional medicine, specifically therapies in Group 1. The therapies in our Groups 3a and b also aim to operate as an alternative to conventional medicine, and have sparse, or non-existent, evidence bases. Those therapies in our Group 2 which aim to operate as an adjunct to conventional medicine, and mainly make claims in the area of relaxation and stress management, are in lesser need of proof of treatment-specific effects but should control their claims according to the evidence available to them (para 4.18).

5. We recommend that if a therapy does gain a critical mass of evidence to support its efficacy, then the NHS and the medical profession should ensure that the public have access to it and its potential benefits (para 4.37).

Regulation (Chapter 5)

6. We recommend that, in order to protect the public, professions with more than one regulatory body make a concerted effort to bring their various bodies together and to develop a clear professional structure (para 5.12).

7. We recommend that each of the therapies in Group 2 should organise themselves under a single professional body for each therapy. These bodies should be well promoted so that the public who access these therapies are aware of them. Each should comply with core professional principles, and relevant information about each body should be made known to medical practitioners and other healthcare professionals. Patients could then have a single, reliable point of reference for standards, and would be protected against the risk of poorly-trained practitioners and have redress for poor service (para 5.23).

8. It is our opinion that acupuncture and herbal medicine are the two therapies which are at a stage where it would be of benefit to them and their patients if the practitioners strive for statutory regulation under the Health Act 1999, and we recommend that they should do so. Statutory regulation may also be appropriate eventually for the non-medical homeopaths. Other professions must strive to come together under one voluntary self-regulating body with the appropriate features outlined in Box 5, and some may wish ultimately to aim to move towards regulation under the Health Act once they are unified with a single voice (paras 5.53 and 5.55).

9. We recommend that each existing regulatory body in the healthcare professions should develop clear guidelines on competency and training for their members on the position they take in relation to their members' activities in well organised CAM disciplines; as well as guidelines on appropriate

training courses and other relevant issues. In drawing up such guidelines the conventional regulatory bodies should communicate with the relevant complementary regulatory bodies and the Foundation for Integrated Medicine to obtain advice on training and best practice and to encourage integrated practice (para 5.79).

10. We encourage the bodies representing medical and non-medical CAM therapists, particularly those in our Groups 1 and 2, to collaborate more closely, especially on developing reliable public information sources. We recommend that if CAM is to be practised by any conventional healthcare practitioners, they should be trained to standards comparable to those set out for that particular therapy by the appropriate (single) CAM regulatory body (para 5.83).

11. We recommend that the MCA find a mechanism that would allow members of the public to identify health products that had met the stringent requirements of licensing and to differentiate them from unregulated competitors. This should be accompanied by strong enforcement of the law in regard to products that might additionally confuse the customer with claims and labelling that resemble those permitted by marketing authorisations (para 5.93).

12. We strongly recommend that the Government should maintain their effective advocacy of a new regulatory framework for herbal medicines in the United Kingdom and the rest of the European Union, and urge all parties to ensure that new regulations adequately reflect the complexities of the unregulated sector (para 5.95).

13. We are concerned about the safety implications of an unregulated herbal sector and we urge that all legislative avenues be explored to ensure better control of this unregulated sector in the interests of the public health (para 5.97).

14. We support the view that any new regulatory regime should respect the diversity of products used by herbal practitioners and allow for simplified

registration of practitioner stocks. Nevertheless, any such regime must ensure that levels of quality and assurance of safety are not compromised (para 5.98).

Professional Training and Education (Chapter 6)

15. Establishing an independent accreditation board along the lines of the British Acupuncture Accreditation Board is a positive move. Other therapies with fragmented professional representation may wish to use this as a model (para 6.20).

16. We recommend that CAM training courses should become more standardised and be accredited and validated by the appropriate professional bodies. All those who deliver CAM treatments, whether conventional health professionals or CAM professionals, should have received training in that discipline independently accredited by the appropriate regulatory body (para 6.33).

17. We suggest that the CAM therapies, particularly those in our Groups 1 and 2, should identify Continuing Professional Development in practice as a core requirement for their members (para 6.34).

18. We consider that it is imperative that higher educational institutions and any regulatory bodies in CAM liaise in order to ensure that training is adequate for registration. If extra training is required after academic qualification to ensure fitness to practise, this should be defined by the appropriate professional body, which should then implement appropriate mechanisms in order to see that this objective is achieved (para 6.40).

19. We recommend that training in anatomy, physiology and basic biochemistry and pharmacology should be included within the education of practitioners of therapies that are likely to offer diagnostic information, such as the therapies in Groups 1 and 3a. Although it may be useful for other therapists to understand basic biomedical science, there is no requirement for such in-depth understanding if the therapy being practised is to be used as an adjunct to conventional medicine (para 6.43).

20. We recommend that every therapist working in CAM should have a clear understanding of the principles of evidence-based medicine and healthcare. This should be a part of the curriculum of all CAM therapy courses. An in-depth understanding of research methods may be even more important for those therapies that operate independently of medical supervision, and which attempt to make a diagnosis and to cure complaints rather than for those which offer relaxation or aim to improve the general quality of life of patients. Therefore training in research and statistical methods may be particularly appropriate for practitioners of therapies in Groups 1 and 3a. But we consider that an understanding of research methods and outcomes should be included in the training of all CAM practitioners. It is important that all of those teaching these courses should understand these principles (para 6.49).

21. We recommend that all CAM training defines limits of the particular therapist's competence as clearly as possible in the state of current knowledge. Training should also give students clear guidance on when a patient should be referred to a primary care physician or even directly to secondary hospital care (para 6.52).

22. We recommend that all CAM therapists should be made aware of the other CAM therapies available to their patients and how they are practised. We do not think it should be assumed that CAM practitioners competent in one discipline necessarily understand the others (para 6.54).

23. We conclude that there should be flexibility for training institutions to decide how to educate practitioners. It is the relevant professional regulatory body of a specific CAM therapy that should set objectives of training and define core competencies appropriate to their particular discipline, and we so recommend. We do not advocate a blanket core curriculum (para 6.61).

24. We recommend that, whether subject to statutory or voluntary regulation, all healthcare regulatory bodies should consider the relevance to their respective professions of those elements set out in paragraph 6.55 (para 6.62).

25. We recommend that therapies with a fragmented professional organisation work with Healthwork UK to develop National Occupational Standards, and we encourage the Department of Health to further support Healthwork UK's activity with such therapies; we believe that this would be of long-term benefit to the public (para 6.70).

26. We recommend that familiarisation should prepare medical students for dealing with patients who are either accessing CAM or have an interest in doing so. This familiarisation should cover the potential uses of CAM, the procedures involved, their potential benefits and their main weaknesses and dangers (para 6.77).

27. We recommend that every medical school ensures that all their medical undergraduates are exposed to a level of CAM familiarisation that makes them aware of the choices their patients might make (para 6.79).

28. We recommend that Royal Colleges and other training authorities in the healthcare field should address the issue of familiarisation with CAM therapies among doctors, dentists and veterinary surgeons by supporting appropriate Continuing Professional Development opportunities (para 6.85).

29. The General Osteopathic and Chiropractic Councils, and any other regulatory bodies, should develop schemes whereby they accredit certain training courses aimed specifically at doctors and other healthcare professionals, and which are developed in conjunction with them. Similar schemes should be pursued by dentists and veterinary surgeons (para 6.95).

30. We recommend that the UKCC work with the Royal College of Nursing to make CAM familiarisation a part of the undergraduate nursing curriculum and a standard competency expected of qualified nurses, so that they are aware of the choices that their patients may make. We would also expect nurses

specialising in areas where CAM is especially relevant (such as palliative care) to be made aware of any CAM issues particularly pertinent to that speciality during their postgraduate training. The Royal College of Nursing and the UKCC, as they do not provide CAM training themselves, should compile a list of courses in CAM that they approve, in order that nurses who wish to practise in this field can obtain guidance on appropriate training (para 6.106).

Research (Chapter 7)

31. To conduct research into the CAM disciplines will require much work and resources, and will therefore be time-consuming. Hence, we recommend that three questions should be prioritised and addressed in the following order:

To provide a starting point for possible improvements in CAM treatment, to show whether further inquiry would be useful, and to highlight any areas where its application could inform conventional medicine does the treatment offer therapeutic benefits greater than placebo?

To protect patients from hazardous practices - is the treatment safe?

To help patients, doctors and healthcare administrators choose whether or not to adopt the treatment - how does it compare, in medical outcome and cost-effectiveness, with other forms of treatment? (para 7.7)

32. We recommend that CAM practitioners and researchers should attempt to build up an evidence base with the same rigour as is required of conventional medicine, using both RCTs and other research designs (para 7.26).

33. To achieve equity with more conventional proposals, we recommend that research funding agencies should build up a database of appropriately trained individuals who understand CAM practice. The research funding agencies could then use these individuals as members of selection panels and committees or as external referees as appropriate (para 7.45).

34. We recommend that universities and other higher education institutions provide the basis for a more robust research infrastructure in which CAM and conventional research and practice can take place side-by-side and can benefit

from interaction and greater mutual understanding. We recommend that a small number of such centres of excellence, in or linked to medical schools, be established with the support of research funding agencies including the Research Councils, the Department of Health, Higher Education Funding Councils and the charitable sector (para 7.57).

35. Bodies such as the Departments of Health, the Research Councils and the Wellcome Trust should help to promote a research culture in CAM by ensuring that the CAM world is aware of the opportunities they offer. The Department of Health should exercise a co-ordinating role. Limited funds should be specifically aimed at training CAM practitioners in research methods. As many CAM practitioners work in the private sector and cannot afford to train in research, we recommend that a number of university-based academic posts, offering time for research and teaching, should be established (para 7.67).

36. We recommend that companies producing products used in CAM should invest more heavily in research and development (para 7.81).

37. We recommend that the NHS R&D directorate and the MRC should pump-prime this area with dedicated research funding 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 MRC programme grants and various training and career development awards available in conventional medicine. The Association of Medical Research Charities may also like to follow this example (para 7.102).

Information (Chapter 8)

38. We recommend that the NHS Centre for Reviews and Dissemination work with the RCCM, the UK Cochrane Centre, and the British Library to develop a comprehensive information source with the help of the CISCOM database, in order to provide comprehensive and publicly available information sources on CAM research, and that resources be made available to enable these organisations to do so (para 8.21).

39. We see the NHS as the natural home in the United Kingdom for reliable, non-promotional information on all types of healthcare; providing such a home is particularly important for CAM, where the diversity of opinion and organisations make it almost impossible for individuals to gain an overview. Consequently we support the plans of the Department of Health to make information on CAM available through NHS Direct, and we urge that they be carried out in the very near future. We recommend that the information should contain not only contact details of the relevant bodies and a list of NHS provision of CAM in each local area, but also some guidance to help patients (and their doctors) evaluate different CAM therapies (para 8.31).

40. We are aware that the National electronic Health Library and NHS Direct Online plan to have information available about CAM in the future and we support these plans and recommend that they are carried forward (para 8.48).

41. We recommend that CAM regulatory bodies, whether statutory or voluntary, remind their members of the laws concerning false claims in advertisements and take disciplinary action against anyone who breaks them. Information leaflets produced by such bodies should provide evidence-based information about a therapy aimed at informing patients, and should not be aimed at selling therapies to patients (para 8.57).

Delivery (Chapter 9)

42. We recommend that those practising privately-accessed CAM therapies should work towards integration between CAM and conventional medicine, and CAM therapists should encourage patients with conditions that have not been previously discussed with a medical practitioner to see their GP. We also urge CAM practitioners and GPs to keep an open mind about each other's ability to help their patients, to make patients feel comfortable about integrating their healthcare provision and to exchange information about treatment programmes and their perceptions of the healthcare needs of patients (para 9.20).

43. We recommend that all NHS provision of CAM should continue to be through GP referral (or by referral from doctors or other healthcare professionals working in primary, secondary or tertiary care) (para 9.37).

44. We recommend that only those CAM therapies which are statutory regulated, or have a powerful mechanism of voluntary self-regulation, should be made available, by reference from doctors and other healthcare professionals working in primary, secondary or tertiary care, on the NHS (para 9.46).

Use of CAM in the United Kingdom

	1999 (%)
Use of any CAM in past 12 months	20
Of which: *	
Herbal **medicine**	34
Aromatherapy	21
Homeopathy	17
Acupuncture / acupressure	14
Massage	6
Reflexology	6
Osteopathy	4
Chiropractic	3

Source: nationally representative random telephone survey of 1204 British adults, commissioned by the BBC. Percentages of those who had used CAM. It must be noted that some individuals use more than one therapy and thus the numbers above do not add up to 100

Use of CAM in the USA

	1990 (%)	1997 (%)
Use of any CAM in past 12 months	33.8†	42.1†
of which‡		
Relaxation techniques	13.1	16.3
Herbal **medicine**	2.5	12.1
Massage	6.9	11.1
Chiropractic	10.1	11.0
Spiritual healing	4.2	7.0
Homeopathy	0.7	3.4
Acupuncture	0.4	1.0

Source: two nationally representative random household telephone surveys.

† Percentages of the total sample population (1539 for the 1990 data; 2055 in 1997).

‡ Table shows selected figures relating to the top five therapies based on the 1997 survey, plus (for comparison with United Kingdom statistics) figures for homeopathy and acupuncture

Reasons for Using CAM

Reason	Percentage of those who use CAM
Helps or relieves injury / condition	25
Just like it	21
Find it relaxing	19
Good health / well-being generally	14
Preventative measure	12
Do not believe conventional **medicine** works	11
Doctor's recommendations / referral	11
To find out about other ways of life / new things	11
Way of life / part of lifestyle	8
Cannot get treatment on NHS / under conventional **medicine**	7

Source: nationally representative random telephone survey of 1204 British adults, commissioned by the BBC

Short and Simplified Descriptions of CAM Disciplines

Group 1: Professionally Organised Alternative Therapies

Acupuncture — Originating from China, acupuncture involves inserting small needles into various points in the body to stimulate nerve impulses. Traditional Chinese acupuncture is based on the idea of 'qi' (vital energy) which is said to travel around the body along 'meridians' which the acupuncture points affect. Western Acupuncture uses the same needling technique but is based on affecting nerve impulses and the central nervous system; acupuncture may be used in the West as an anaesthetic-agent and also as an analgesic.

Chiropractic — Used almost entirely to treat musculo-skeletal complaints through adjusting muscles, tendons and joints and using manipulation and massage techniques. Diagnostic procedures include case histories, conventional clinical examination and x-rays. Chiropractic was originally based on the idea that 'reduced nerve flow' led to disease.

Herbal medicine — A system of medicine which uses various remedies derived from plants and plant extracts to treat disorders and maintain good health. Another term for this type of treatment is phytotherapy.

Homeopathy — A therapy based on the theory of treating like with like. Homeopathic remedies use highly diluted substances that if given in higher doses to a healthy person would produce the symptoms that the dilutions are being given to treat. In assessing the patient homeopaths often take into account a range of physical, emotional and lifestyle factors which contribute to the diagnosis.

Osteopathy — A system of diagnosis and treatment, usually by manipulation, that mainly focuses on musculo-skeletal problems, but a few schools claim benefits across a wider spectrum of disorders. Historically differs from chiropractic in its underlying theory that it is impairment of blood supply and not nerve supply that leads to problems. However in practice there is less

difference than might be assumed. Mainstream osteopathy focuses on musculo-skeletal problems; but prior to osteopathy gaining statutory protection of title, other branches of this therapy purported to diagnose and treat a range of disorders. One such branch is now known as cranio-sacral therapy, which should be considered as a distinct therapy which would fall into Group 3.

Group 2*:* Complementary Therapies

Alexander Technique — Based on a theory that the way a person uses their body affects their general health. This technique encourages people to optimise their health by teaching them to stand, sit and move according to the body's 'natural design and function'. This is, in essence, a taught technique, rather than a therapy.

Aromatherapy — Use of plant extract essential oils inhaled, used as a massage oil, or occasionally ingested. Common in France but practised there by medical doctors only. Can be used to alleviate specific symptoms or as a relaxant.

Bach and other flower remedies -— The theory behind flower remedies is that flowers contain the life force of the plant and this is imprinted into water through sun infusion which is used to make the flower remedy. Flower remedies are often used to help patients let go of negative thoughts; usually flower remedies are ingested.

Body work therapies, including massage — Therapies that use rubbing, kneading and the application of pressure to address aches, pains and musculo-skeletal problems. Often used as a relaxant.

Counselling stress therapy — A series of psychical therapies that attempt to help patients to work through their thoughts and to reflect on their lives so as to maximise wellbeing.

Hypnotherapy — The use of hypnosis in treating behavioural disease and dysfunction, principally mental disorders.

Meditation — A series of techniques used to relax a patient to facilitate deep reflection and a clearing of the mind (see Maharishi Ayurvedic Medicine below).

Reflexology — A system of massage of the feet based on the idea that there are invisible zones running vertically through the body, so that each organ has a corresponding location in the foot. It has also been claimed to stimulate blood supply and relieve tension.

Shiatsu — A type of massage originating from Japan which aims to stimulate the body's healing ability by applying light pressure to points across the body. Relies on the meridian system of 'qi' in a similar way to traditional Chinese medicine and acupuncture.

Healing — A system of spiritual healing, sometimes based on prayer and religious beliefs, that attempts to tackle illness through non-physical means, usually by directing thoughts towards an individual. Often involves 'the laying on of hands'.

Maharishi Ayurvedic Medicine * — A system which promotes transcendental meditation, derived from the Vedic tradition in India. Recommends the use of herbal preparations similar to those used in Ayurvedic Medicine (see below) and Traditional Chinese medicine (see below).

Nutritional medicine — Term used to cover the use of nutritional methods to address and prevent disease. Uses diets and nutritional supplements. Often used to address allergies and chronic digestive problems. The difference between nutritional medicine and dietetics is that nutritional therapists work independently in accordance with naturopathic principles and focus on disorders which they believe can be attributed to nutritional deficiency, food intolerance or toxic overload. They believe these three factors are involved in a wide range of health problems. Dieticians usually work under medical supervision, using diets to encourage healthy eating and tackle a narrower

range of diseases. Nutritional therapists often use exclusion diets and herbal remedies to tackle patients' problems.

Yoga — A system of adopting postures with related exercises designed to promote spiritual and physical well-being.

Group 3: *Alternative Disciplines*

3a: *Long-established and traditional systems of healthcare*

Anthroposophical medicine — 'Anthroposophy' describes people in terms of their physicality, their soul and their spirit. Anthroposophical medicine aims to stimulate a person's natural healing forces through studying the influence of their soul and spirit on their physical body.

Ayurvedic Medicine — An ancient discipline, originating in India, based upon the principle of mind- spirit-body interaction and employing natural herbs, usually mixtures, in treatment.

*Chinese Herbal Medicine** — (See Traditional Chinese medicine below) A tradition of medicine used for thousands of years in China, which has its own system of diagnosis. Uses combinations of herbs to address a wide range of health problems.

Eastern Medicine (Tibb)* — Tibb is a tradition which synthesises elements of health philosophy from Egypt, India, China and classical Greece. It literally means 'nature'. The concept of wholeness and balance permeates the principle of Tibb. Imbalance is thought to cause disease. It is thought to occur on four levels: physical, emotional, mental and spiritual. Tibb uses a range of treatments including massage, manipulation, dietary advice and herbal medicine, and a psychotherapeutic approach to restore imbalances which are considered the cause of disease.

Naturopathy — A method of treatment based on the principle that the natural laws of life apply inside the body as well as outside. Uses a range of natural approaches including diet and herbs and encourages exposure to sun and fresh air to maximise the body's natural responses.

Traditional Chinese medicine — The theory behind Traditional Chinese medicine is that the body is a dynamic energy system. There are two types of energy - Yin qi and Yang qi - and it is thought if there is an imbalance in Yin and Yang qi then symptoms occur. Traditional Chinese medicine uses a number of treatment methods to restore the balance of Yin and Yang qi; these include acupuncture, herbal medicine, massage and the exercise technique Qigong.

3b: *Other alternative disciplines*

Crystal therapy — Based on the idea that crystals can absorb and transmit energy and that the body has a continuing fluctuating energy which the crystal helps to tune. Crystals are often placed in patterns around the patient's body to produce an energy network to adjust the patient's energy field or 'aura'.

Dowsing — Traditionally used as a way to identify water sources underground. Is not itself a therapy but is used by a range of other disciplines to answer questions through intuitive skills. Often used in conjunction with Radionics.

Iridology — A method of diagnosing problems and assessing health status that relies on studying the iris of the eye and noting marks and changes.

Kinesiology — A manipulative therapy by which a patient's physical, chemical, emotional and nutritional imbalances are assessed by a system of muscle testing. The measurement of variation in stress resistance of groups of muscles is said to identify deficiencies and imbalances, thus enabling diagnosis and treatments by techniques which usually involve strengthening the body's energy through acupressure points.

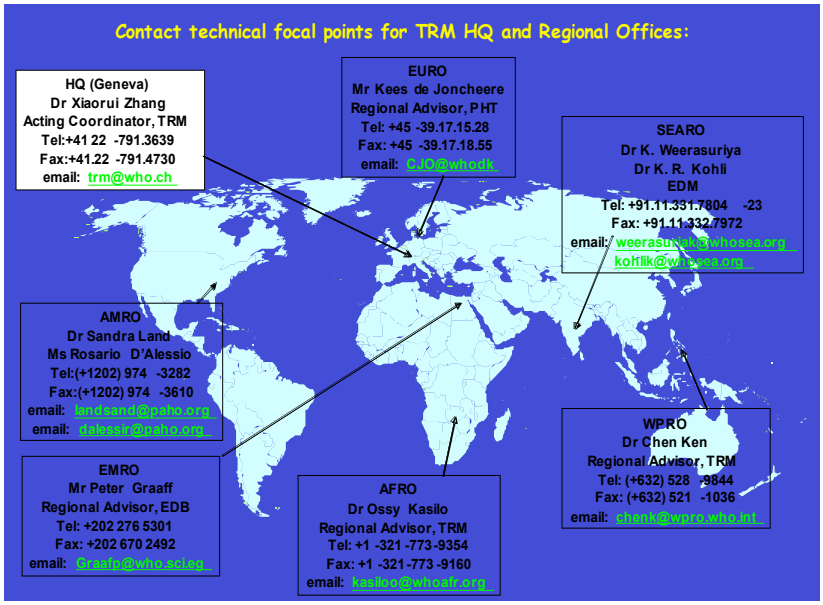
Radionics — A type of instrument-assisted healing which attempts to detect disease before it has physically manifested itself. It is based on the belief that everyone is surrounded by an invisible energy field which the practitioner tunes into and then attempts to correct problems which have been identified. Practitioners believe it can be done over long distances. Instruments are a focus of the healer's intent and include sugar tablets which carry the healing 'idea'.

ORGANIZZAZIONE MONDIALE DELLA SANITA'

L'Organizzazione Mondiale della Sanità ha pubblicato nell'anno 2000 le "**General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine"**, frutto del lavoro di oltre cento esperti che, dopo avere redatto nel 1997 a Rockville nel Maryland le prime bozze di queste Linee Guida, hanno prodotto questo documento, grazie anche all'apporto dei Centri che collaborano con l'OMS nell'ambito della Medicina Tradizionale e delle Medicine Non Convenzionali, come il National Center for Complementary and Alternative Medicine (NCCAM) degli Stati Uniti d'America e del National Institutes of Health, Bethesda, MD, USA.

Questo documento di circa ottanta pagine tratta insieme della metodologia della ricerca e della valutazione "evidence based" sia della Medicina Tradizionale sia delle Medicine Non Convenzionali o CAM, secondo l'acronimo in uso nel mondo anglosassone.

Nella figura sono riportati i Centri che collaborano con l'OMS in questo ambito.



Nel 2002 l'OMS ha pubblicato il suo primo documento globale sulla Medicina Tradizionale e sulle Medicine Non Convenzionali dal titolo:

"WHO Traditional Medicine Strategy 2002-2005".

L'enorme mole di lavoro che ha prodotto questo documento si è svolto sotto il coordinamento del Dr Xiaorui Zhang (Acting Team Coordinator, Traditional Medicine, Department of Essential Drugs and Medicines Policy, World Health Organization, Avenue Appia 20, 1211 Geneva 27, Switzerland, zhangx@who.int).

Commonly used TM/CAM therapies and therapeutic techniques

	Chinese medicine	Ayurveda	Unani	Naturopathy	Osteopathy	Homeopathy	Chiropractic	Others
Herbal medicines	●	●	●	●	■	●		●[a]
Acupuncture/ acupressure	●				■			■[b]
Manual therapies	Tuina[c]	●	●	▣	●		●	Shiatsu[d]
Spiritual therapies	●	●	●	●				Hypnosis, healing, meditation
Exercises	Qigong[e]	Yoga		Relaxation				

● – commonly uses this therapy/therapeutic technique
■ – sometimes uses this therapy/therapeutic technique
▣ – uses therapeutic touch

[a] for example, many informal TM systems in Africa and Latin America use herbal medicines.
[b] for example, in Thailand, some commonly used TM therapies incorporate acupuncture and acupressure.
[c] type of manual therapy used in traditional Chinese medicine.
[d] refers to manual therapy of Japanese origin in which pressure is applied with thumbs, palms, etc., to certain points of the body.
[e] component of traditional Chinese medicine that combines movement, meditation and regulation of breathing to enhance the flow of vital energy (qi) in the body to improve circulation and enhance immune function.

Table 2 **Examples of countries with an integrative approach to TM/CAM**

	National policy on TM/CAM	TM/CAM unit or department within ministry of health	Regulation of herbal products and herbal products industry	Human TM resources	Practice at all levels including public hospitals (i.e. if practised in public hospitals, TM/CAM are integrated into national health system)	Health insurance coverage for treatment and products	TM/CAM national research institutes	Official education at university level that covers both TM and AM for doctors, pharmacists and nurses
China	1949 constitution contains policy on TM	State Administration of Traditional and Complementary Medicine (TCM)	Regulation – Yes Pharmacopoeia includes herbs List of essential drugs includes herbal medicines Manufacturers 600 Herbal farmers 340 000	TCM doctors 525 000 TCM/AM doctors 10 000 TCM pharmacists 83 000 TCM associate doctors 72 000 AM pharmacists 55 000	TCM hospitals 2 500 TCM/AM hospitals 39 Total beds 35 000 TM hospitals for minority groups 127	Full	170 national and state research institutes	30 TCM universities 3 TM colleges for minority groups 51 medical technology schools of TCM
Republic of Korea	National TM policy 1969	Oriental Medicine Bureau	Regulation – Yes Pharmacopoeia includes herbs	Oriental doctors 9 914 Acupuncturists 4 500	107 oriental medical hospitals and 6 590 local oriental medical clinics	Full	1 national research institute	11 oriental medicine universities
Viet Nam	National TM policy 1955	Department of TM	Regulation – Yes List of essential drugs includes herbal medicines State manufacturers 2	TM doctors 25 500 Acupuncturists 20 000 TM practitioners 5 000	48 hospitals with TM department	Full	3 national research institutes	TM faculty in 3 medical colleges, 2 medical technology schools of TM

Sources: compiled from government reports to World Health Organization.

Table 3 **Examples of countries with an inclusive approach to TM/CAM**

	National policy on TM/CAM	TM/CAM unit or department within ministry of health	Regulation of TM or herbal products or of both TM and herbal products	TM/CAM practised at all levels including public hospitals (i.e. if practised in public hospitals, TM/CAM are integrated into national health system)	Health insurance coverage for treatment and products	TM/CAM research institute at national or university level	Official education at university level, covering both TM + AM for doctors, pharmacists and nurses
India	Yes	Yes	Both	Yes in some hospitals	No	Yes	Yes
Sri Lanka	Yes	Yes	Both	No	No	No	No
Indonesia	Yes	Yes	Both	Yes, in some state hospitals	No	Yes	No
Japan	No	No	Both	Yes, in some state hospitals	Yes	Yes, in some prefectures	No
Australia	No	Yes, in some states	Herbal products	Yes, in some state hospitals	Partial	No	Yes
United Arab Emirates	No	No	Both	Yes, in some state hospitals	No	Yes	No
Germany	No	No	Both	Yes, in some state hospitals	Partial	Yes	No
Norway	Yes	Staff in charge	Both	Yes, in some state hospitals	Partial	Yes, in one state university	No
United Kingdom	Yes	No	Both	Yes, in some state hospitals	Partial	No	No, in preparation
Canada	Yes	Yes	Both	Yes, in some state hospitals	Partial	Yes, in some state universities	No
USA	No	No	Both	Yes, in some state hospitals	Partial	Yes, NCCAM and in some state universities	No
Ghana	Yes	Yes	Both	No	No	Yes	No
Nigeria	Yes	Yes	Both	Yes	No	Yes	No

Sources: compiled from government reports to World Health Organization.

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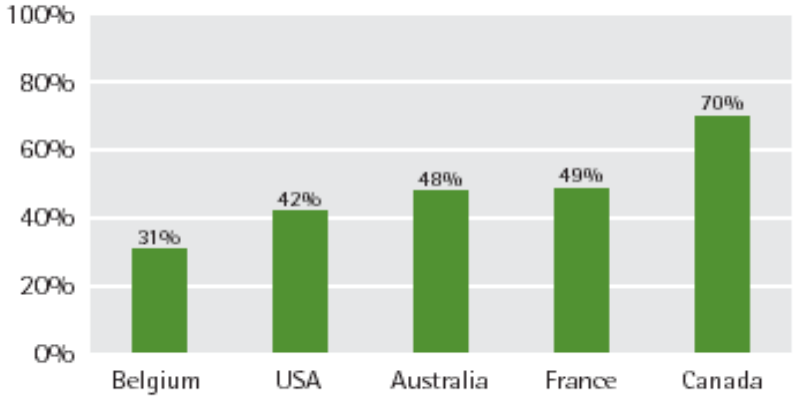
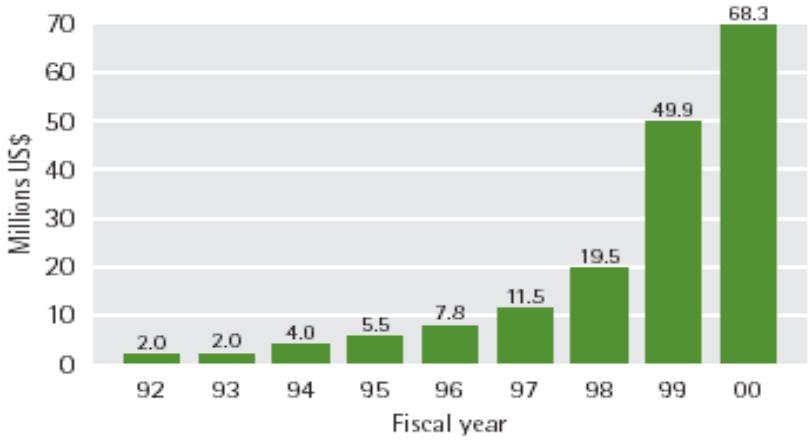
Percentage of population which has used CAM at least once in selected developed countries



Sources: Fisher P & Ward A, 1999; Health Canada, 2001, World Health Organization, 1998.[7,8,6]

CAM funding is increasing significantly in the USA



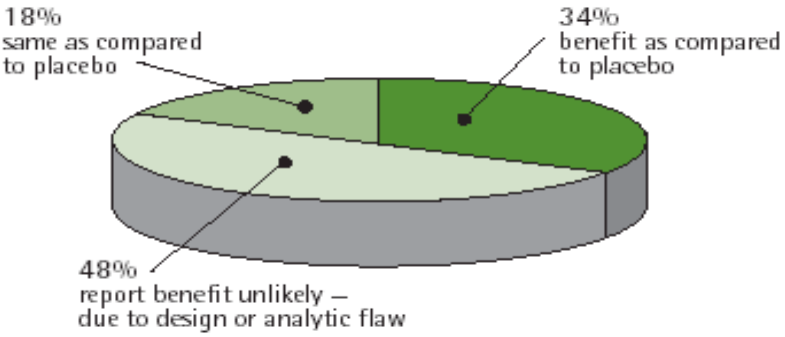
Source: National Center for Complementary and Alternative Medicine, 2000.[45]

TM/CAM challenges fall into four categories	
National policy and regulatory frameworks	• Lack of official recognition of TM/CAM and TM/CAM providers • TM/CAM not integrated into national health care systems • Lack of regulatory and legal mechanisms • Equitable distribution of benefits of indigenous TM knowledge and products • Inadequate allocation of resources for TM/CAM development and capacity building
Safety, efficacy and quality	• Lack of research methodology • Inadequate evidence-base for TM/CAM therapies and products • Lack of international and national standards for ensuring safety, efficacy and quality control of TM/CAM therapies and products • Lack of adequate regulation and registration of herbal medicines • Lack of registration of TM/CAM providers • Inadequate support for research
Access	• Lack of data measuring access levels and affordability • Need to identify safe and effective therapies and products • Lack of official recognition of role of TM/CAM providers • Lack of cooperation between TM/CAM providers and allopathic practitioners • Unsustainable use of medicinal plant resources
Rational use	• Lack of training for TM/CAM providers and on TM/CAM for allopathic practitioners • Lack of communication between TM/CAM and allopathic practitioners, and between allopathic practitioners and consumers • Lack of information for public on rational use of TM/CAM

Key elements to include in a national policy on TM/CAM

- Definition of TM/CAM.
- Definition of government's role in developing TM/CAM.
- Provision for safety and quality assurance of TM/CAM therapies and products.
- Provision for creation or expansion of legislation relating to TM/CAM providers and regulation of herbal medicines.
- Provision for education and training of TM/CAM providers.
- Provision for promotion of proper use of TM/CAM.
- Provision for capacity building of TM/CAM human resources, including allocation of financial resources.
- Provision for coverage by state health insurance.
- Consideration of intellectual property issues.

Good evidence of efficacy exists for some herbal medicines — but too often evaluation is inadequate



% of randomized clinical trials (RCTs) showing benefit of herbal medicines (based on 50 RCTs with 10 herbal medicines for 18 therapeutic indications)

Source: based on data in Herbal Medicines: an Evidence-based Look. Therapeutics Letter, *Issue 25, June–July 1998.*

Key needs in ensuring the safety, efficacy and quality of TM/CAM

At national level:

- National regulation and registration of herbal medicines.
- Safety monitoring for herbal medicines and other TM/CAM.
- Support for clinical research into use of TM/CAM for treating country's common health problems.
- National standards, technical guidelines and methodology, for evaluating safety, efficacy and quality of TM/CAM.
- National pharmacopoeia and monographs of medicinal plants.

At global level:

- Access to existing knowledge of TM/CAM through exchange of accurate information and networking.
- Shared results of research into use of TM/CAM for treating common diseases and health conditions.
- Evidence-base on safety, efficacy and quality of TM/CAM products and therapies.

Priority areas for research

- Effects of each individual therapy: efficacy, safety and cost-effectiveness.
- Research into mechanisms of action of individual therapies, including patterns of response to treatment.
- Research into TM/CAM genre itself, including social research into motivation of patients seeking TM/CAM and usage patterns of TM/CAM.
- Research into new research strategies which are sensitive to the TM/CAM paradigm.
- Research into efficacy of diagnostic methods used.
- Research into implementation and effects of TM/CAM in specific health care settings.

Source: House of Lords, 2000.[16]

Key needs in increasing availability and affordability of TM/CAM

At national and global levels:

- Identification of safest and most effective TM/CAM therapies and products (including: evidence that the therapy is effective; evidence that the therapy is safe; evidence that the therapy is cost-effective).
- Research into safe and effective TM/CAM treatment for diseases that represent the greatest burden, particularly for poorer populations.
- Recognition of role of TM practitioners in providing health care in developing countries.
- Optimized and upgraded skills of TM practitioners in developing countries.
- Indigenous TM knowledge protected and preserved.
- Sustainable cultivation of medicinal plants.

Key needs in promoting sound use of TM/CAM by providers and consumers

At national level:

- Training guidelines for most commonly used TM/CAM therapies.
- Strengthened and increased organization of TM/CAM providers.
- Strengthened cooperation between TM/CAM medicine providers and allopathic medicine practitioners.
- Reliable information for consumers on proper use of TM/CAM therapies and products.
- Improved communication between allopathic medicine practitioners and their patients concerning latter's use of TM/CAM.

Critical indicator

Strategy objective	Number of WHO Member States reporting a national TM/CAM policy/ Total number of WHO Member States	1999 status	2005 target
WHO Member States with national policy on TM/CAM	25/191	13%	25%

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

Objectives	Components	Expected outcomes
POLICY: Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies* and programmes	1. Recognition of TM/CAM 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
	2. Protection and preservation of indigenous TM knowledge relating to health 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
SAFETY, EFFICACY AND QUALITY: Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge-base on TM/CAM, and by providing guidance on regulatory and quality assurance standards	3. Evidence-base for TM/CAM 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
	4. Regulation of herbal medicines 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
	5. Guidelines on safety, efficacy and quality 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
ACCESS: Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations	6. Recognition of role of TM/CAM practitioners in health care 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
	7. Protection of medicinal plants 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
RATIONAL USE: Promote therapeutically sound use of appropriate TM/CAM by providers and consumers	8. Proper use of TM/CAM by providers 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
	9. Proper use of TM/CAM by consumers 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

** With the exception of China, the Democratic People's Republic of Korea, the Republic of Korea and Viet Nam, such integration has nowhere taken place. This underlines the fact that in some countries national assessment is needed to ascertain which TM/CAM modalities can be best integrated with the national health care system.*

Critical indicator

Strategy objective	Number of WHO Member States reporting laws and regulations on herbal medicines/Total number of WHO Member States	1999 status	2005 target
WHO Member States with laws and regulations on herbal medicines	65/191	34%	40%

Critical indicators

Strategy objective	Number of WHO Member States with national research institute[l] for TM/CAM/Total number of WHO Member States	1999 status	2005 target
WHO Member States with national research institute for TM/CAM	19/191	10%	18%

Riporto le definizioni che l'OMS dà nel "**General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine":**

Traditional Medicine (TRM)

Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Complementary/Alternative Medicine (CAM)

The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system.

Herbal Medicines include:

- herbs including crude plant material such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
- herbal materials including, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages or other materials.
- herbal preparations are the basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.
- finished herbal products consisting of herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product can also be used. Finished herbal products and mixture herbal products may contain

excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.

Traditional use of herbal medicines

herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations. Traditional use of herbal medicines refers to the long historical use of these medicines. Their use is well established and widely acknowledged to be safe and effective, and may be accepted by national authorities.

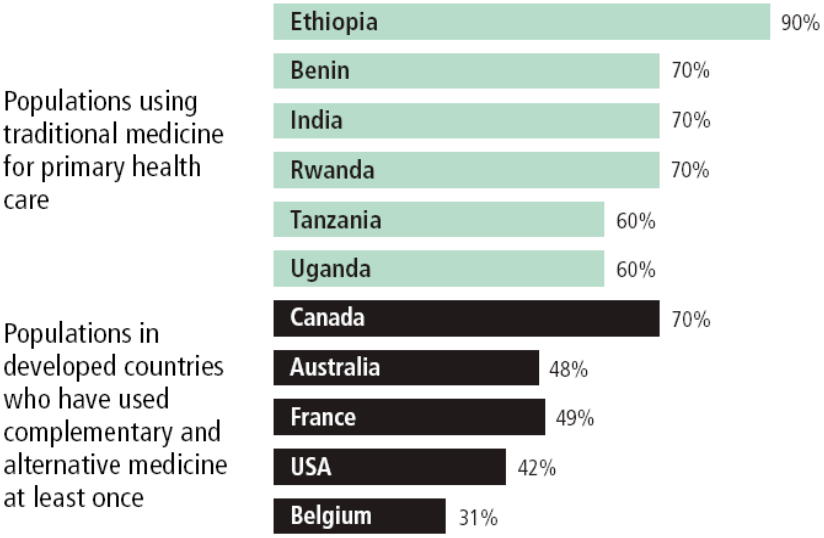
Therapeutic activity

therapeutic activity refers to the successful prevention, diagnosis and treatment of physical and mental illnesses; improvement of symptoms of illnesses; as well as beneficial alteration or regulation of the physical and mental status of the body.

Active ingredients

active ingredients refer to ingredients of herbal medicines with therapeutic activity. In herbal medicines where the active ingredients have been identified, the preparation of these medicines should be standardized to contain a defined amount of the active ingredients, if adequate analytical methods are available. In cases where it is not possible to identify the active ingredients, the whole herbal medicine may be considered as one active ingredient.

Figure 1 Many developing country populations use TM to help meet health care needs, while many populations in developed countries have used CAM at least once



Sources: Eisenberg DM et al, 1998; Fisher P & Ward A, 1994; Health Canada, 2001; World Health Organization, 1998; and government reports submitted to WHO.

Box 1 What is traditional medicine?

Traditional medicine includes diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness.

Commonly used therapies and therapeutic techniques

	Chinese Medicine	Ayurveda	Unani	Naturopathy	Osteopathy	Homeopathy	Chiropractic
Herbal medicines	●	●	●	●	■	●	
Acupuncture/acupressure	●				■		
Manual therapies	■	●	●	▣	●		●
Spiritual therapies	●	●	●	●			
Exercises	■	■		■			

● = *commonly incorporates this therapy/therapeutic technique*
■ = *sometimes incorporates this therapy/therapeutic technique*
▣ = *incorporates therapeutic touch*

[1] The term "traditional medicine" (TM) is used throughout most of this paper. But in some developed countries, the term "complementary and alternative medicine" (CAM) is used where the dominant health care system is based on allopathic medicine, or where TM has not been incorporated into the national health care system.

[2] Traditional medicine *practitioners* are generally understood to be traditional healers, bone setters, herbalists, etc. Traditional medicine *providers* include both traditional medicine practitioners and allopathic medicine professionals such as doctors, dentists and nurses who provide TM/CAM therapies to their patients – e.g. many allopathic doctors also use acupuncture to treat their patients.

Box 2 Key messages for policy-makers

- TM includes diverse health practices, approaches, knowledge and beliefs, incorporating medicines from plant, animal and/or mineral sources, spiritual therapies, manual techniques and exercises.
- TM is widely and increasingly used for a wide spectrum of diseases by people in both developed and developing countries.
- A growing number of countries are adopting national policies on TM and developing specific regulatory capacity, especially for herbal medicines. Increasingly, countries are defining the role that TM plays in national health care delivery systems.
- Scientific evidence from randomized clinical trials is strong for many uses of acupuncture, for some herbal medicines and for some of the manual therapies.
- Nevertheless, much of the scientific literature on TM provides inadequate evidence on safety and efficacy: individual case reports and patient series, with no control or comparison group.
- Over-harvesting of medicinal plants threatens some ecosystems.
- Protection and preservation of TM knowledge is essential to ensure access to traditional forms of health care and respect for those who hold TM knowledge. Intellectual property rights issues require national and international attention.

Box 3 Policies and actions checklist

Safety, efficacy and quality

- Establish registration and licensing of providers.
- Establish national regulation and registration of herbal medicines.
- Establish safety monitoring of herbal medicines and other TM therapies.
- Provide selective support for clinical research into use of TM for treating country's common health problems.
- Develop national standards, and technical guidelines and methodology, for evaluating safety, efficacy and quality of TM.
- Develop national pharmacopoeia and monographs of medicinal plants.

Access

- Identify safe and effective TM therapies and products.
- Support research into safe and effective treatment for those diseases which represent the greatest burden, particularly for poorer populations.
- Recognize role of TM providers in providing health care.
- Optimize and upgrade the skills of TM providers.
- Protect TM knowledge through recording and preservation.
- Cultivate and conserve medicinal plants to ensure their sustainable use.

Rational use

- Develop training guidelines for country's most commonly used TM therapies.
- Strengthen and increase organization of TM providers.
- Strengthen cooperation between TM providers and other health care providers.
- Make reliable information on proper use of TM therapies and products available for consumers.
- Improve communication between health care providers and their patients concerning use of TM.

Table 1 WHO traditional medicine strategy 2002–2005: objectives, components and expected outcomes

Objectives	Components	Expected outcomes
POLICY: Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies* and programmes	**1. Recognition of TM/CAM** Help countries to develop national policies and programmes on TM/CAM	1.1 Increased government support and recognition of TM/CAM, through comprehensive national policies on TM/CAM 1.2 Relevant TM/CAM integrated into national health care system services
	2. Protection and preservation of indigenous TM knowledge relating to health 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
SAFETY, EFFICACY AND QUALITY: Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge base on TM/CAM, and by providing guidance on regulatory and quality assurance standards	**3. Evidence base for TM/CAM** 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
	4. Regulation of herbal medicines 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 therapies
	5. Guidelines on safety, efficacy and quality 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
ACCESS: Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations	**6. Recognition of role of TM/CAM providers in health care** Advocate recognition of TM/CAM providers in health care by encouraging interaction and dialogue between TM/CAM providers 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 TM/CAM through national health services 6.3 Increased number of national organizations of TM/CAM providers
	7. Protection of medicinal plants 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
RATIONAL USE: Promote therapeutically sound use of appropriate TM/CAM by providers and consumers	**8. Proper use of TM/CAM by health providers** 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
	9. Proper use of TM/CAM by consumers 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 practioners and their patients concerning use of TM/CAM

** With the exception of China, the Democratic People's Republic of Korea, the Republic of Korea and Viet Nam, such integration has nowhere taken place. In some countries national assessment will therefore be needed to ascertain which TM/CAM modalities can be best integrated into the national health care system.*

STATI UNITI D'AMERICA

Dal **"2nd International Scientific Conference on Complementary, Alternative and Integrative Medicine Research"**, April 12-14, 2002, Boston, Massachusetts, USA, riporto il riassunto, i cui dati sono eloquenti:

Overview of Complementary and Alternative Medicine

A series of consumer surveys conducted between 1990 and the present have tracked CAM use in the United States by prevalence, cost, and use patterns. Findings from these studies included the following:

- The prevalence of CAM use increased from 25% in 1990 to 42% in 1997.

This growth represents increased usage among all socioeconomic groups.

The prevalence of herbal remedy use increased by 380% during the same time period.

- Total visits to CAM providers in 1997 (629 million) exceeded total visits to all primary care physicians (386 million) during that year.

- Estimated consumer expenditures for CAM professional services in 1997 totaled $21 billion.

- In 1997, an estimated 15 million adults took prescription medications concurrently with herbal remedies or high-dose vitamins, and were thus at risk for drug-herb or drug-supplement interactions.

- The extent to which patients disclose CAM use to physicians remains low. In both 1990 and 1997, fewer than 40% of CAM therapies used were disclosed to a physician.

- CAM use appears to increase with age. Three in 10 pre-baby boomers, 5 in 10 baby-boomers, and 7 in 10 post-baby boomers reported use of at least 1 CAM therapy by the age of 33 years.

- Reasons for CAM use included perceived efficacy, particularly in combination with conventional therapies; more congruence with patient values and beliefs; and failed conventional treatment.

- The majority of participants surveyed believed that physicians know little about dietary supplements. An estimated 72% would continue using these even if a government scientific study showed negative effects; 81% supported FDA regulation of products prior to sale of the product.

Nel marzo 2002 la Commissione istituita col Decreto Esecutivo n. 13147 dal Presidente degli Stati Uniti per studiare, regolare e definire in ogni aspetto la pratica delle Medicine Non Convenzionali ha portato a termine, dopo due anni dalla sua costituzione, il proprio compito emanando il più voluminoso e completo documento mai redatto sulla politica sanitaria delle Medicine Non Convenzionali, dal titolo: "**White House Commission on Complementary and Alternative Medicine Policy, Final Report"**.

Questo documento, in cui grande attenzione viene posta a quanto è risultato dal Sixth Report del House of Lords, rappresenta, a mio avviso il riferimento imprescindibile per qualsiasi futuro confronto tra le politiche nazionali per tentare di dare omogeneità alla materia.

Dall' Executive Summary si riportano le Linee Guida Federali:

"Based on its mission and responsibilities, the Commission endorsed the following 10 guiding principles to shape the process of making recommendations and to focus the recommendations themselves:

1. A wholeness orientation in health care delivery. Health involves all aspects of life-mind, body, spirit, and environment-and high-quality health care must support care of the whole person.

2. Evidence of safety and efficacy. The Commission is committed to promoting the use of science and appropriate scientific methods to help identify safe and effective CAM services and products and to generate evidence that will protect and promote the public health.

3. The healing capacity of the person. People have a remarkable capacity for recovery and self-healing, and a major focus of health care is to support and promote this capacity.

4. Respect for individuality. Each person is unique and has the right to health care that is appropriately responsive to him or her, respecting preferences and preserving dignity.

5. The right to choose treatment. Each person has the right to choose freely among safe and effective care or approaches, as well as among qualified practitioners who are accountable for their claims and actions and responsive to the person's needs.

6. An emphasis on health promotion and self-care. Good health care emphasizes self-care and early intervention for maintaining and promoting health.

7. Partnerships as essential to integrated health care. Good health care requires teamwork among patients, health care practitioners (conventional and CAM), and researchers committed to creating optimal healing environments and to respecting the diversity of all health care traditions.

8. Education as a fundamental health care service. Education about prevention, healthy lifestyles, and the power of self-healing should be made an integral part of the curricula of all health care professionals and should be made available to the public of all ages.

9. Dissemination of comprehensive and timely information. The quality of health care can be enhanced by promoting efforts that thoroughly and thoughtfully examine the evidence on which CAM systems, practices, and products are based and make this evidence widely, rapidly, and easily available.

10. Integral public involvement. The input of informed consumers and other members of the public must be incorporated in setting priorities for health care and health care research and in reaching policy decisions, including those related to CAM, within the public and private sectors.

CAM is a heterogeneous group of medical, health care, and healing systems other than those intrinsic to mainstream health care in the United States.

While" complementary and alternative medicine" is the term used in this report, the Commission recognizes that the term does not fully capture all of the diversity with which these systems, practices, and products are being used by consumers, CAM practitioners, and mainstream health care institutions.

The Commission recognizes that most CAM modalities have not yet been scientifically studied and found to be safe and effective. The fact that many Americans are using CAM modalities should not be confused with the fact that most of these modalities remain unproven by high-quality clinical studies. The Commission believes that conventional and CAM systems of health and healing should be held to the same rigorous standards of good science.

Therefore, substantially more funding for research is needed to determine the possible benefits and limitations of a variety of CAM modalities, especially those that are already in widespread use. Well-designed scientific research and demonstration projects can help to determine which CAM modalities and approaches are clinically effective and cost-effective. With information from these studies, the public can make informed, intelligent decisions about their own health and well-being and the appropriate use of CAM interventions.

Conventional and CAM practitioners also will benefit from the dissemination of this information.

Although most CAM modalities have not yet been proven safe and effective, it is likely that some of them eventually will be, whereas others will not. The recommendations and actions in this report constitute a road map to help guide research and policy decisions over the next several years as more scientific and other information becomes available. In this context, many of the recommendations and actions may be useful immediately. Others may be more useful once a greater body of scientific evidence has been developed and made available.

The Commission also notes the lack of an appropriate definition of complementary and alternative medicine and the need to differentiate between

interventions that have been, or have the potential to be, found safe and effective and those that lack any scientific evidence of safety or effectiveness. Including the entire mix of CAM interventions under one umbrella fails to identify the merits and shortcomings of specific interventions. It is essential to begin separating the safe from the unsafe and the effective from the ineffective. Likewise, the heterogeneous array of education, training, and qualifications of CAM practitioners has made it difficult for the Commission to clearly and succinctly target its recommendations. This limitation must be addressed during the process of implementing the recommendations and actions.

Coordination of Research

The public's increased use of CAM has added urgency to the need to examine the safety and effectiveness of CAM practices and products and to discover the basic mechanisms underlying them. Basic, clinical, and health services research in CAM are essential for including CAM in the mainstream health care system.

In addition, the growing influence of consumers on the health care system has created a need for more population-based research on CAM use and for public participation in shaping the direction of CAM research. Federal requirements and opportunities for such participation currently exist. Public members of Federal advisory committees, as well as the agencies they advise, would gain from orientation and training programs on how to provide input most effectively.

Support for Research

The NCCAM at the NIH is an example of how quality research in CAM can be executed by a Federal agency. Similar efforts should now be extended to other Federal agencies. These agencies with research and health care responsibilities need to assess the scope of scientific, clinical practice, health services, and public needs regarding CAM that are related to their missions and develop funding strategies to address them. Federal support is particularly

needed for research on CAM products that are unpatentable and those that are frequently used by the public but unlikely to attract private research dollars. Congress and the Administration should consider simultaneous legislative and administrative incentives to stimulate private sector investment in such products. Also, CAM approaches that appear to be effective but may not attract private investment, should be considered for Federal support.Federal, private, and nonprofit sector support is essential to developing a body of evidence-based knowledge about CAM. Among the areas in need of study are the complex compounds and mixtures found in CAM products, multiple-treatment interventions, the effect of patient-practitioner interactions on outcomes, the individualization of treatments, modalities designed to improve self-care and promote wellness behaviors, and core questions posed by CAM that might expand our understanding of health and disease.

The Commission commends the National Center for Complementary and Alternative Medicine (NCCAM) for its leadership and contributions to CAM research, methodology, research training, and infrastructure development and supports increases in these crucial activities, including database development and information dissemination. In addition, NCCAM should collaborate with 1) the Institute of Medicine, to develop guidelines for establishing research priorities in CAM and to address the ambiguity regarding definitions of CAM, thus making it easier to decide how to allocate resources; 2) the National Science Foundation, to examine frontier areas of science associated with CAM that lie outside the current research paradigm and to develop methodological approaches to study them; and 3) the World Health Organization, to study traditional systems of medical practice from a variety of cultures.

The Commission also recognizes the work of the Office of Dietary Supplements, the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine, the National Library of Medicine, and the other components of the National Institutes of Health (NIH) that are supporting

research and related activities in CAM and recommends that they continue their efforts.

Scope of Research

A dialogue between CAM and conventional medicine appears to be emerging and efforts should be made to strengthen it. CAM and conventional medical practitioners and researchers; accredited research institutions; Federal and state research, health care, and regulatory agencies; private and nonprofit organizations; and the general public need to be included in the dialogue. Communication and cooperation are essential to improving the quality of CAM research and to the success of research applications.

The same high standards of quality, rigor, and ethics must be met in both CAM and conventional research, research training, publication of results in scientific, medical, and public health journals, presentations at research conferences, and review of products and devices. Properly qualified CAM and conventional medical professionals should be represented on research, journal, regulatory, and health insurance review and advisory committees.

Investigators engaged in research on CAM must ensure that people participating in clinical studies receive the protections to which they are entitled and which are required for all human subjects in clinical research. Moreover, licensed, certified, or otherwise authorized practitioners who are engaged in research on CAM should not be sanctioned solely because they are engaged in such research, as long as 1) their studies are well designed and approved by an appropriately constituted institutional review board (IRB), 2) they are following the requirements for the protection of human subjects, and 3) they are meeting their professional and ethical responsibilities. All CAM and conventional practitioners, whether they are engaged in research or not, must meet whatever state practice requirements or standards govern their authorization to practice. IRBs that review CAM research studies need the

expertise of qualified CAM professionals, and accredited CAM institutions and professional organizations should establish IRBs whenever possible.

Publication of research results in recognized peer-reviewed research journals is needed to provide reliable information about CAM to researchers, clinical practitioners, health services professionals, third party payors and the public. In addition, the decisions of third-party payers regarding access to and reimbursement for CAM therapies should be based on published evidence.

Public and private resources can be used to conduct and update systematic reviews of the research literature on CAM. The Agency for Health Care Research and Quality (AHRQ) should expand its systematic reviews of CAM systems and treatments for use by private and public entities, and NCCAM and AHRQ should issue and regularly update a comprehensive, understandable summary of current clinical evidence in CAM for health care practitioners and the public.

Research Training and Infrastructure

Sustained, adequate funding is essential to building and maintaining a strong infrastructure for training skilled CAM researchers and conducting rigorous research. Federal agencies that have training programs as part of their health care missions should support training that addresses CAM-related questions relevant to their missions. Academic health centers at conventional institutions are gradually developing venues for exchanging experiences with CAM professionals regarding the training of conventional researchers in CAM practices, the introduction of CAM practitioners to the conventional research culture, and inclusion of CAM in research, research training, clinical, and medical education activities. Accredited CAM institutions are gradually expanding their capacity to conduct research and research training and to establish cooperative arrangements with conventional medical health centers. Public and private resources should be increased to strengthen the

infrastructure for CAM research and research training at conventional medical and CAM institutions.

Education and Training of Health Care Practitioners

Because the public uses both CAM and conventional health care, the education and training of conventional health professionals should include CAM, and the education and training of CAM practitioners should include conventional health care. The result will be conventional providers who can discuss CAM with their patients and clients, provide guidance on CAM use, collaborate with CAM practitioners, and make referrals to them, as well as CAM practitioners who can communicate and collaborate with conventional providers and make referrals to them.

The education and training of all practitioners should be designed to ensure public safety, improve health, increase the availability of qualified and knowledgeable CAM and conventional practitioners, and enhance collaboration among them. Education and training programs can do this by developing curricula and programs that facilitate communication and foster collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations.

Conventional health professional schools, postgraduate training programs, and continuing education programs should develop core curricula regarding CAM to prepare practitioners to discuss CAM with their patients and clients and help them make informed choices about the use of CAM. The challenges to developing these core curricula include:

- *Professional, organizational, and institutional resistance to change,*
- *Lack of funding,*
- *Inadequate incentives to adopt the curricula,*
- *Logistical design, development, and implementation difficulties,*
- *Lack of consensus on curricula,*
- *Lack of adequately trained faculty and faculty development, and*

- *Limited ability to add to already very full curricula.*

Likewise, CAM education and training programs need to develop core curricula that reflect the fundamental elements of biomedical science and conventional health care as they relate to and are consistent with the CAM practitioners' scope of practice. The challenges to developing such core curricula for CAM education are similar to those stated above.

Support for CAM Programs, Faculty, and Students

Access to increased funding and other resources for CAM faculty, curricula, and program development at both CAM and conventional institutions could result in better CAM education and training, which, in turn, could translate into more skilled practitioners, improved CAM services, and greater patient satisfaction and safety. Faculty development is essential for improved CAM education and training at CAM and conventional institutions. Currently, funding is limited and appears to be directed toward only a small number of curricula and program development projects at largely conventional institutions. Increased Federal, state, and private support should be made available to expand and evaluate CAM faculty, curricula, and program development at accredited CAM and conventional institutions.*

CAM students, institutions, and professional organizations have expressed considerable interest in participating in loan and scholarship programs. Currently, the only CAM students eligible for participation in the Scholarship for Disadvantaged Students program are chiropractic students. No CAM students are eligible for the National Health Service Corps Scholarship program at this time.

In general, expansion of Federal loan programs to CAM students appears easier to accomplish than participation in the scholarship program. The Department of Health and Human Services (DHHS) should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners can enhance or expand health care provided by primary care

teams. The feasibility study could be followed with demonstration projects to determine what types of CAM practitioners, education and training requirements, practice sites, and minimal clinical competencies result in improved health outcomes

Additional Education and Training in CAM

To improve the competency of practitioners and the quality of services, CAM education and training should continue beyond the entry, professional school, or qualifying degree level. However, before establishing new CAM postgraduate education and training programs or expanding current ones, appropriate CAM candidates must be identified and the feasibility, type, duration, and impact of the programs determined.

Since community health centers represent a unique opportunity for combining education in ethnically, racially, and culturally diverse learning environments with service to medically underserved populations who otherwise might not have access to CAM, current and proposed CAM postgraduate education and training programs affiliated with such centers should be given special consideration.

Continuing education can provide a powerful means of affecting conventional and CAM practitioners' behavior, thereby enhancing public health and safety.

Currently, the number, type, and availability of programs with content appropriate for all practitioners who provide CAM services and products are not sufficient.

Therefore, continuing education programs need to be improved and made available to all conventional health professionals as well as to all practitioners who provide CAM services and products.

Development and Dissemination of Information about CAM

One of society's greatest achievements-and one of its greatest challenges-has been the dramatic improvement in the development and dissemination of information. Not only does information travel faster, significantly more of it has

become available. This is especially true of health information, including information about CAM.

To ensure public safety in the continually evolving area of CAM, accurate information must be available so that people can make informed choices. This includes choosing the most appropriate type of practitioner, deciding what type of approach can benefit certain conditions, ascertaining the ingredients in a product (such as a dietary supplement), and determining whether ingredients are safe and can assist in maintaining health. Yet far too often information to help make these choices is nonexistent, inaccurate, or difficult to find.

The ready availability of accurate information is especially important to people who are confronting a life-threatening illness. For someone newly diagnosed with a serious or life-threatening illness, seeking information about their disease and treatment options is often their first course of action. Many people quickly become overwhelmed by the vast array of often conflicting information that is available, and yet for some diseases and conditions, there is a scarcity of reliable information.

Promoting Accurate, Easily Accessible Information

To be effective, information must be tailored to the population it seeks to reach. People of different cultural, ethnic, and socioeconomic backgrounds frequently have different views of health and healing, different patterns of use of health care services and products, and different ways of acquiring information. People's views and behaviour also vary with their age, literacy, and specific health conditions. Informational materials need to reflect the characteristics and behaviour of the target population.

The Federal government should make accurate and easily accessible information on CAM practices and products available to the public. It can do this by establishing a task force to facilitate the development and dissemination of CAM information within the Federal government and to eliminate existing

gaps in information about CAM. In addition, more librarians can be trained to help consumers find information on CAM.

The Internet has given people access to vast amounts of health care information that would not have been available to them previously, but this technology raises concerns about quality. People may be making life-and-death decisions based on information that is misleading, incomplete, or inaccurate. This is particularly true in the case of CAM, for which a broad base of evidence is not yet available.

Establishing a public-private partnership to develop voluntary standards for CAM information on the Internet, and conducting a public education campaign to help people evaluate information, should improve the quality and accuracy of CAM information from this source. Actions should also be taken to protect consumers' privacy.

Training, licensing requirements, certification, and scope of practice; regulations; and even definitions of CAM practitioners can vary considerably. Therefore, practitioners' qualifications should be readily available to consumers to help them make informed choices about selecting and using practitioners. Information on State regulations, requirements, and disciplinary actions should also be readily available to help ensure consumers' safety.

Consumers frequently learn about CAM products and services through advertising and marketing. While most advertisers of CAM products and services comply with current laws, misleading and fraudulent health claims do exist. Some people, particularly those who are ill, who have limited language or educational skills, or who lack access to the conventional health care system, are especially susceptible to advertisements that promise to cure a disease, symptom, or problem. Not only are some of these products, services, and treatments ineffective, they may even be harmful, especially if they delay necessary treatment or take money away from persons with limited resources. Efforts to enforce existing laws curbing such abuses should be increased.

Ensuring the Safety of CAM Products

One of the most rapidly growing areas in CAM has been the use of dietary supplements. Sales of these products totaled $17 billion in 2000, and more than 158 million consumers used them. Dietary supplements are not subject to the same rigorous testing and oversight required of prescription drugs, which are targeted toward disease conditions. While this has greatly increased the public's access to supplements, it has limited the information required on the label regarding potential risks, benefits, and appropriate use.

The public expects that products sold in the United States are safe. Since many dietary supplements are purchased without the knowledge or advice of an appropriately trained and credentialed provider, information on ingredients, benefits, appropriate use, and potential risks should be made easily available to consumers at the time of purchase, especially information affecting vulnerable consumers such as children, the elderly, pregnant or nursing women, and people with certain health conditions or compromised immune systems.

CAM products that are available to U.S. consumers must be safe and meet appropriate standards of quality and consistency. Efforts to ensure the development of analytical methods and reference materials for dietary supplements should be increased. Good Manufacturing Practices for Dietary Supplements should be published expeditiously, followed by timely review of comments and completion of a final rule. The Food and Drug Administration (FDA) will need adequate resources to complete this task. Federal agencies responsible for enforcing current laws monitoring the quality of imported raw materials and finished products intended for use as dietary supplements will also require adequate funding.

Manufacturers should have on file and make available to the FDA upon request scientific information to substantiate their determinations of safety, and current statutory provisions should be reexamined periodically to determine whether safety requirements for dietary supplements are adequate. An objective process

for evaluating the safety of dietary supplement products should be develop by an independent expert panel.

Reporting of adverse events associated with dietary supplements is voluntary: Manufacturers and distributors are not required to notify the FDA of adverse reactions that have been reported to them. Congress should require dietary supplement manufacturers to register their products and suppliers with the FDA.

Until this requirement is in place, the agency should encourage voluntary registration so that manufacturers, suppliers, and consumers can be notified promptly if a serious adverse event is identified. Dietary supplement manufacturers and suppliers should be required to maintain records and report serious adverse events to the FDA.

Additional resources and support are needed to simplify the adverse event reporting system for dietary supplements. The system should be made easier to use, its database streamlined to permit timely review and follow-up on reports received, and its outreach to consumers and health professionals (including poison control centers, emergency room physicians, CAM practitioners, and midlevel marketers) improved. Simplifying the adverse event reporting system will improve both manufacturers' and consumers' awareness of and participation in voluntary reporting.

To ensure the safety of the public and to give consumers confidence in the products they are using, Congress should periodically evaluate the effectiveness, limitations, and enforcement of the Dietary Supplement Health and Education Act of 1994 and take appropriate action when needed.

Access and Delivery

The Commission heard numerous concerns about access to CAM practitioners and products, including access to qualified CAM practitioners, state regulation of CAM practitioners, integration of CAM and conventional health care, collaboration between CAM and conventional practitioners, and the cost of

CAM services. Many people expressed a desire for increased access to safe and effective CAM, along with conventional services. The Commission recognizes that Americans want to be able to choose from both conventional and CAM practices and that they want assurances that practitioners are qualified.

Improving Access to CAM

As is true of conventional health care, many factors influence access to CAM services and their delivery. The distribution and availability of local providers, regulation and credentialing of providers, policies concerning coverage and reimbursement, and characteristics of the health care delivery system all affect the quality and availability of care and consumer satisfaction. Equally important, access is limited by income, since most CAM practices and products are not covered under public or private health insurance programs. Moreover, access is more difficult for rural, uninsured, underinsured, and other special populations. The issue of access is further compounded by the lack of scientific evidence for many CAM practices and products.

A better understanding of how the public uses CAM is needed to determine what can be done to improve access to safe and effective CAM within the context of other public health and medical needs. In additional, more information is needed on what constitutes "appropriate access" to CAM services.

A few community health centers have begun to use the services of CAM practitioners, such as chiropractors, naturopathic physicians, and acupuncturists.

These centers might provide models for other community health centers and public health service programs, but first their impact on access to care and the cost-benefit picture needs to be determined. Hospice care for the terminally ill is another important model of care that should be evaluated. Some hospice programs are beginning to include CAM practitioners on the treatment team.

The Federal government should support demonstration projects that integrate safe and effective CAM services into the health care programs of hospices and community health centers.

Special populations, such as racial and ethnic minorities, and vulnerable populations, such as the chronically and terminally ill, have unique challenges and needs regarding access to CAM. Yet efforts to address their access to CAM must take into consideration their need for access to conventional health care, and scare resources must be allocated carefully. The Federal government should facilitate and support the evaluation of CAM practices to help meet the health care needs of these populations and support practices found to be safe and effective. Ways of supporting the practice of indigenous healing in the United States and improving communication among indigenous healers, conventional health care professionals, and CAM practitioners should also be identified.

Now is the time to look at policy options for the future and to design strategies for addressing potential issues of access and safety. A variety of issues need to be considered: protecting the public, maintaining free competition in the provision of CAM services, and maintaining the consumer's freedom to choose appropriate health professionals. The need to maintain CAM styles of practice, rather than allowing them to be subsumed into the conventional medical model, also must be considered when addressing the issue of access.

To improve consumers' access to safe and effective CAM practices and qualified practitioners, and to ensure accountability, the Federal government should evaluate current barriers and develop strategies for removing them. It should also help states evaluate the impact of state legislation on access to CAM practices and on public safety. Health care workforce data and other studies can help identify current and future health care needs and the relevance of safe and effective CAM services to those needs.

Ensuring CAM Practitioners' Accountability to the Public

States should consider whether a regulatory infrastructure for CAM practitioners is necessary to promote quality of care and patient safety and to ensure practitioners' accountability to the public. The Federal government should offer assistance to states and professional organizations in developing and evaluating guidelines for practitioner accountability and competence, including regulation of practice and periodic review and assessment of the effects of regulations on consumer protection. When appropriate, states should implement provisions for licensure, registration, and exemption that are consistent with a practitioner's education, training, and scope of practice.

Nationally recognized accrediting bodies should evaluate how health care organizations are using CAM practices and develop strategies for the safe and appropriate use of qualified CAM practitioners. In partnership with other public and private organizations, they should evaluate the present use of CAM practitioners in health care delivery settings and develop strategies for their appropriate use in ways that will benefit the public. Current standards and guidelines should be reviewed to ensure safe use of CAM practices and products in health care delivery organizations.

Coverage and Reimbursement

The coverage and reimbursement policies of public and private organizations that pay for, provide, or insure conventional health care services have played a crucial role in shaping the health care system-and they will play an increasingly important role in determining the future of CAM and its place in the nation's health care system.

Coverage of CAM services and products varies among purchasers of health plans, but employer-sponsored plans appear more likely than others to offer them. These plans generally offer a chiropractic benefit, and a growing number cover acupuncture and massage therapy. When offered, CAM coverage often places a ceiling on the number of visits, restricts the clinical applications, and

specifies the qualifications of the practitioner. Typically, CAM is offered as a supplemental benefit rather than as a core or basic benefit. Benefit designs also include discount programs, in which covered individuals pay reduced fees for services provided by a network of CAM practitioners, and annual benefit accounts against which services may be purchased.

Barriers to Coverage

Overcoming barriers to coverage and reimbursement will require first amassing scientific evidence to assess the benefits and cost-effectiveness of CAM and then giving equitable, impartial consideration to those practices and products proven to be safe and effective. Gathering a body of evidence will require DHHS, other Federal agencies, states, and private organizations to develop a health services research agenda and to increase funding for studies of the outcomes of CAM interventions in treating acute, chronic, and life-threatening conditions. Research, demonstrations, and evaluations should focus not only on safety but also on clinical effectiveness, costs, and the ratio of costs to benefits. In addition, health services research can be used to support the development and study of models for providing safe and effective CAM within the nation's health care system. Prototypes should include integrative and collaborative models for CAM and conventional health care, comparisons of conventional and CAM treatments for the same condition, and evaluations of various combinations of services and products. Information on health services research should be made available through the clearinghouse of NCCAM.

To conduct health services research, investigators need data from claim and encounter forms, specifically data coded using nationally accepted, standardized systems. National coding systems such as Common Procedure Terminology recognize some CAM interventions, but they are currently limited in scope and specificity. More recently, a coding system for CAM procedures, services, and products-ABCcodes-has been developed and is being used in a number of settings. The National Committee for Vital and Health Statistics and

DHHS should authorize a national coding system that supports standardized data on CAM for use in clinical and health services research. In addition, the coding system should support practitioners and insurers who cover CAM services in complying with the electronic claims requirements of the Health Insurance Portability and Accountability Act.

Any medical or health care intervention that has undergone scientific investigation and has been shown to improve health or functioning, or to be effective in treating the chronically or terminally ill, should be considered for inclusion in health plan coverage. To accomplish this, health insurance and managed care organizations should modify their benefit design and coverage processes in order to offer purchasers health benefit plans that include safe and effective CAM interventions. Similarly, purchasers should enhance the processes they use to develop health benefits and give consideration to safe and effective CAM interventions. DHHS can support these efforts by convening work groups and conferences to assess the state-of-the-science of CAM services and products and to develop consensus and other types of guidance for Medicare, other public and private purchasers, health plans, and even consumer representatives. Coverage of and reimbursement for most health care services are linked to a provider's ability to furnish services legally within the scope of his or her practice. This legal authority to practice is given by the state in which services are provided. Thus, even if insurers, managed care organizations, and other health plan sponsors are interested in covering safe, cost-effective CAM interventions, they cannot do so unless properly licensed, or otherwise legally authorized, practitioners are available in a state. State governments are encouraged to consider how regulation of CAM practitioners could affect coverage and thirdparty reimbursement of safe and effective CAM interventions.

Criteria for Using CAM

Once a CAM service is covered, health insurers, managed care organizations, and government agencies must be able to determine whether use of the service or product in a particular situation is generally accepted or investigational, and whether the service or product is medically necessary in that situation. Few criteria are available to guide practitioners in deciding the medical or clinical necessity of CAM interventions. DHHS, preferably through a centralized CAM office, should work with health care and professional associations, CAM experts, health insurance and managed care organizations, benefits experts, and others to guide changes in health plan coverage for safe and effective CAM services and products and to develop criteria for use of CAM interventions.

Purchasers, health insurers, and managed care organizations will need CAM expertise when developing changes in coverage and reimbursement policies that involve CAM. CAM practitioners and experts should be included on advisory bodies and work groups considering CAM benefits and other appropriate health benefit issues.

CAM in Wellness and Health Promotion

In recent years, people have come to recognize that a healthful lifestyle can promote wellness and prevent illness and disease, and many people have used CAM approaches to attain this goal. Wellness is defined in many ways, but all agree that it is more than the absence of disease. Wellness can include a broad array of activities and interventions that focus on the physical, mental, spiritual, and emotional aspects of one's life. The concomitant rise in interest in CAM and in wellness and prevention presents many new and exciting opportunities for the health care system.

CAM's Role in Attaining the Nation's Health Goals

Since 1979, the U.S. Public Health Service has led a national initiative to define goals and objectives for the nation's health. As is clear from the

resulting Healthy People series, a wide range of disciplines and social institutions is needed to improve health and wellness, prevent illness and disease, and manage disabilities and chronic conditions. The effectiveness of the health care delivery system in the future will depend upon its ability to make use of all approaches and modalities that provide a sound basis for promoting health.

There is evidence that certain CAM practices, such as acupuncture, biofeedback, yoga, massage therapy, and tai chi, as well as certain nutritional and stress reduction practices may be useful in contributing to the achievement of the nation's health goals and objectives. Federal agencies and public and private organizations should evaluate CAM practices and products that have been shown to be safe and effective to determine their potential for promoting wellness and helping to achieve the nation's health promotion and disease prevention goals. Demonstration programs should be funded for those determined to be beneficial

The Federal government, in partnership with public and private organizations, should support the development of a national campaign that teaches and encourages healthful behaviors for all Americans, including children. The campaign would focus on improving nutrition, promoting exercise, and teaching stress management. Safe and effective CAM practices and products should be included, where appropriate. The role of safe and effective CAM practices and products in the workplace should also be evaluated, and incentives should be developed to encourage the use of those found to be beneficial. The application of CAM wellness and prevention practices to the management of chronic disease and disabilities is a largely unexplored area. CAM principles and practices may be useful not only in preventing some of these diseases and conditions, but also in enhancing recovery and preventing further illness.

Increased research in this area will help to determine how CAM principles and practices can best be used to meet the goals of the health care system. DHHS and other Federal agencies should fund demonstration projects to evaluate the clinical and economic impact of comprehensive health promotion programs that include CAM. These studies should include underserved and special populations.

Wellness and Health Promotion in Programs for Special and Vulnerable Populations

Early interventions that promote the development of good health habits and attitudes could help prevent many of the negative behaviors and lifestyle choices that begin in childhood or adolescence. Poor dietary habits, lack of exercise, smoking, suicide, substance abuse, homicide, and depression are epidemic among young people. The Commission believes that it is time for wellness and health promotion to be made a national priority. CAM practices and products that have been shown to be appropriate for children and young people should be included in this effort, which must involve all sectors of the community, particularly schools.

The Federal government funds many programs that serve vulnerable populations, such as children, the poor, and the elderly. The programs have a direct impact on the health and quality of life of the people they serve, and they may benefit from a wellness and prevention component that includes safe and effective CAM practices and products. The agencies that administer these programs should evaluate safe and effective CAM practices and products to determine their applicability to the programs and fund demonstration projects for those found to be beneficial.

Federally funded health care delivery programs, such as the Department of Veterans Affairs, The Department of Defense, the Indian Health Service, community and migrant health centers, maternal and child health programs, and school health programs, should also evaluate the applicability of CAM

wellness and prevention activities to their services. Demonstration programs should be funded for CAM practices and products found to be beneficial to these populations. Other Federal, State, public, and private health care delivery systems and programs would also be well-advised to evaluate CAM practices and products to determine their applicability to programs and services that help promote wellness and health.

The Secretary of Health and Human Services should bring together public and private health care organizations to evaluate the contribution of safe and effective CAM practices and products to wellness and health and to determine how they may be used in health systems and programs, especially in the nation's hospitals and long-term care facilities and in programs serving the aged, persons with chronic illness, and those at the end of life. CAM and conventional health professional training programs should offer students training and education in self-care and lifestyle decision-making, both to improve practitioners' health and to enable them to impart this knowledge to their patients or clients.

Coordinating Federal CAM Efforts

Integration of safe and effective CAM practices and products into the nation's health care system will require an ongoing, coordinated Federal presence. Establishment of a centralized office is the most effective means of accomplishing this goal. Responsibilities of the office should include:

- *Coordinating Federal CAM activities,*
- *Serving as a Federal CAM policy liaison with conventional health care and CAM professionals, organizations, educational institutions, and commercial ventures,*
- *Planning, facilitating, and convening conferences, workshops, and advisory groups,*
- *Acting as a centralized point of contact for the public, CAM practitioners, conventional health care providers, and the media,*

- *Facilitating implementation of the recommendations and actions of the White House Commission on Complementary and Alternative Medicine Policy, and*
- *Exploring additional and emerging topics not included in the Commission's Executive Order.*

The Commission recommends that the President, Secretary of Health and Human Services, or Congress create an office to coordinate Federal CAM activities and to facilitate the integration of safe and effective practices and products into the nation's health care system. The office should be established at the highest possible appropriate level in DHHS and be given sufficient staff and budget to meet its responsibilities. The office should charter an advisory council whose members would include representatives of the private and public sectors as well as CAM and conventional practitioners with the necessary expertise, diversity of backgrounds, and training to guide and advise the office about its activities".