6 March 1997 A4-0075/97

REPORT

on the status of non-conventional medicine

Committee on the Environment, Public Health and Consumer Protection

Rapporteur: Mr P. Lannoye

PE 216.066/fin.

C O N T E N T S

At the sitting of 27 October 1994 the President of Parliament announced that he had referred the motion for a resolution on complementary or non conventional medicine tabled pursuant to Rule 45 of the Rules of Procedure by Mr Pimenta and others to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Legal Affairs and Citizens' Rights and the Committee on Social Affairs and Employment for their opinions.

At its meeting of 23 November 1994 the Committee on the Environment, Public Health and Consumer Protection decided to draw up a report and, by letter of 28 November 1994, duly requested authorization. At the sitting of 16 January 1995 the President announced that the Conference of Presidents had authorized the committee to report on the subject.

The Committee on the Environment, Public Health and Consumer Protection appointed Mr Lannoye rapporteur at its meeting of 20 December 1994.

It considered the draft report at its meetings of 7 May 1996, 9 July 1996, 3 September 1996 and 27 February 1997.

At the last meeting it adopted the motion for a resolution by 21 votes to 4, with 2 abstentions.

The following were present for the vote: Collins, chairman; Lannoye, rapporteur and vice-chairman; Alber (for Burtone), Aparicio Sánchez (for Apolinario), Baldi (for d'Aboville), Bébéar, Blokland, Breyer, Corbett (for Bowe), Correia (for Hulthén), De Coene (for Kokkola), Díez de Rivera Icaza, Eisma, Feret, Florenz, Garosci (for Cabrol), Gränitz, Hardstaff (for van Putten), Kirsten M. Jensen, McKenna, Kestelijn-Sierens (for Olsson), Kronberger, Kuhn, Liese (for Jackson), Marinucci, Needle, Pollack, Roth-Behrendt, Sornosa Martinez (for Bertinotti), Tamino, Trakatellis, White.

The opinion of the Committee on Legal Affairs and Citizens' Rights is attached; the Committee on Social Affairs and Development decided on 24 March 1995 not to deliver an opinion.

The report was tabled on 6 March 1997.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

A.

MOTION FOR A RESOLUTION

Resolution on the status of non-conventional medicine

The European Parliament,

-having regard to the motion for a resolution by the following Members: Pimenta, Dell'Alba, Diez de Rivera Icaza, Crowley, Ewing, González Alvarez and Lord Plumb on 'complementary medicine' (or non-traditional medicine) (B4-0024/94),

-having regard to its resolution of 13 June 1991 on a directive widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products[1] ,

-having regard to Council Directive 92/73/EEC[2] widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products,

-having regard to budgetary heading B6-8332 of the 1994 EC budget, to heading B6-7142, penultimate paragraph, of the 1995 EC Budget and to paragraphs 4 and 5 of heading B6-7142 of the 1996 EC Budget, which provide for ECU 1 m for 'research on the effectiveness of other therapeutic methods such as chiropractic, osteopathy, acupuncture, naturopathy, Chinese medicine, anthroposophic medicine, phytotherapy, etc.',

-having regard to the report by the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Legal Affairs and Citizens' Rights, (A4-0075/97),

A.whereas a number of people in the Member States are making use of certain non-conventional medicines and therapies and it would be unrealistic to ignore this de facto state of affairs,

B.whereas the view, shared by a number of doctors, is increasingly widely held, that different methods of treatment and different approaches to health and illness are not

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[1] OJ C 183, 15.7.1991, p. 332

[2] OJ L 297, 13.10.1992, p.8.

mutually exclusive, but can on the contrary be used to complement one another,

C. whereas it is important to ensure that patients have the broadest possible choice of therapy, guaranteeing them the maximum level of safety and the most accurate information possible on the safety, quality, effectiveness and possible risks of so-called non-conventional medicines, and that they are protected against unqualified individuals,

D. whereas the whole corpus of medical systems and therapeutic disciplines covered by the term 'non-conventional medicine' is either not recognized as valid, or only partially so; whereas a given medical or surgical treatment applied instead of another may be described as 'alternative', and a treatment used to supplement another treatment may be described as 'complementary'; whereas it would be wrong to speak about 'alternative' or 'complementary' disciplines insofar as the fact of a medical discipline's being alternative or complementary can only be determined from the specific context within which it is being used; whereas an alternative medical discipline may also be a complementary one; whereas, in this report, the term 'non-conventional medicine' covers the notions of 'alternative medicine', 'natural medicine' and 'complementary medicine' as used indiscriminately in certain Member States to designate medical disciplines other than conventional medicine,

E. whereas, in order to protect the health of his own patients to the full, a doctor may use all resources and knowledge in any field of medicine in accordance with his own judgment and conscience,

F. whereas there is a broad range of non-conventional medical disciplines, and some of them enjoy some form of legal recognition in certain Member States and/or possess an organizational structure at European level (common basic training, deontological code, etc.) in particular chiropractic, homeopathy, anthroposophical medicine, Chinese traditional medicine (including acupuncture), shiatsu, naturopathy, osteopathy, phytotherapy, etc.; whereas there is a broad range of non-conventional medical disciplines but only a certain number of them meet all the following criteria: a form of legal recognition in certain Member States, an organizational structure at European level and self-regulatory mechanisms,

G. having regard to the EC Treaty and specifically Title III, Articles 52 to 66 thereof, on the free movement of persons and freedom of establishment; whereas these freedoms are undermined by the heterogeneous prevailing situation with regard to the status and recognition of all the non-conventional medical disciplines within the European Union; whereas the freedom to exercise their profession which

certain health practitioners currently enjoy in their countries should under no circumstances be limited by modifying the status or the degree of recognition enjoyed by these disciplines at European level, nor by limiting the freedom of choice of therapy enjoyed by patients with regard to non-conventional medical treatment; having regard to the provisions of the Treaty in respect of the Member States and, more specifically, those laid down in Article 57(1), (2) and (3),

H. whereas there are already clear signs of developments, whether in the form of national legislation in certain Member States liberalizing the practice of non-conventional medicine while reserving certain specific activities for authorized practitioners (the 'Beroepen in de Individuele Gezondheidszorg' law adopted on 9 November 1994 by the Netherlands Senate), or specific regulations (UK law on osteopaths in 1993 and on chiropractic in 1994, legislation on chiropractic in Denmark in 1991, Sweden in 1989 and in Finland), or by making the training official (chiropractic in the UK and the Nordic countries), or the introduction of medicines into the pharmacopoeia (anthroposophical medicine in Germany),

I. whereas European legislation concerning the status and the practice of non-conventional medicine may provide patients with guarantees; whereas each type of medicine should be obliged to organize the profession at European level (deontological code, professional registers, and training criteria),

J. whereas it is first of all necessary clearly to identify each of the non-conventional medical disciplines; whereas to this end, clinical trials, evaluation of results of treatment, basic research (operating mechanisms of action) and other scientific studies or academic research should evaluate the effectiveness of the therapies applied; whereas this evaluation must be carried out according to the appropriate methodologies for the various disciplines,

K. whereas the regulation and coordination of training criteria imposed on the practitioners of non-conventional medical disciplines would constitute an essential guarantee for citizens; whereas it is essential, in the interests of both patients and practitioners, that qualifications be harmonized at a high level as a result of a rigorous self-regulatory process within the profession itself, subsequently leading to the award of a state diploma meeting the specific requirements of each discipline; whereas the levels of training must be appropriate to the specific nature of various non-conventional medical disciplines,

L. whereas the training of conventional medical practitioners should include an introduction to certain non-conventional medical disciplines,

M. whereas, if therapists are to have the opportunity to exercise their profession properly and if, at the same time, patients are to be provided with guarantees that non-conventional medicines will be carefully assessed, the European Pharmacopoeia should include the full range of pharmaceutical and herbal products used in non-conventional medicine; whereas, for the same reason, it is necessary to review Directives 65/65/EEC, 75/319/EEC and 92/73/EEC and Regulation 2309/93 establishing the European Agency for the Evaluation of Medicinal Products, so as to provide patients with guarantees as to the quality and safety of non-conventional medicines,

N. whereas the Council in its resolution 95/C 350/05 of 30 November 1995 on medicinal plant preparations[3] calls on the Commission to clarify the 'legal status of medicinal plant preparations, having regard to the Community provisions on proprietary medical products' and to study 'the specific conditions required to ensure the protection of public health',

O. whereas there is a need to indicate the quality, effectiveness and safety of the therapeutic products under consideration and provide for the publication of monographs on each product,

P. whereas given the current state of legislation, legislation in the field of food supplements (vitamins, oligo-elements etc.) would help protect consumers without restricting their freedom of access and of choice, and would guarantee that qualified practitioners were at liberty to prescribe such products,

Q. whereas the development and introduction where possible of non-conventional medicines in the livestock farming sector would be particularly important with a view to the more effective protection of consumers from pharmacological residues in meat products and better conditions for livestock currently being reared, in view of the rules soon to be introduced concerning organic livestock farming techniques,

R. whereas a transition phase will be necessary in order to allow all those currently practising to meet the requirements of the new legislation; whereas it will be necessary to set up an 'equivalence commission' with the remit of examining the situation of the practitioners concerned on a case-by-case basis,

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[3] OJ C 350, 30 December 1995, p.6.

1. Calls on the Commission, if the results of the study allow, to launch a process of recognizing non-conventional medicine and, to this end, to take the necessary steps to encourage the establishment of appropriate committees;

2. Calls on the Commission to carry out a thorough study into the safety, effectiveness, area of application and the complementary or alternative nature of all non-conventional medicines and to draw up a comparative study of the various national legal models to which non-conventional medical practitioners are subject; urges the Commission to use both studies as a basis for any coordinating legislation on non-conventional medicine; calls on the Commission, giving priority to several non-conventional medical disciplines which already enjoy some form of recognition and organization at European level, to submit the draft directive required to guarantee freedom of establishment and provision of services for non-conventional medical practitioners (as provided for by Article 57(3) of the Treaty), and freedom of access to the therapeutic products necessary for them to exercise their professions, and consequently to review existing legislation on the medical profession and the therapeutic products necessary for the practice of these disciplines;

3. Calls on the Commission, in formulating European legislation on non-conventional forms of medicine, to make a clear distinction between non-conventional medicines which are 'complementary' in nature and those which are 'alternative' medicines in the sense that they replace conventional medicine;

4. Calls on the Council and European Parliament after completion of the preliminary work referred to in paragraph 2 of this report to promote the development of research programmes in the field of non-conventional medicines taking account of individual and collective behaviour and the preventive role and specific characteristics of non-conventional medical disciplines;

5. Urges the Commission to submit a report as soon as possible to the Council and European Parliament on the results of the studies and research already carried out under budget item B-7142 which, since 1994, has been earmarked for research into the effectiveness of homeopathy and other non-conventional medicines;

6. Calls on the Commission, in examining the effectiveness of forms of therapy used in non-conventional medicine, to ensure that none of the treatments used in the Member States makes use of medicines made from the organs of threatened animal species, which would constitute involvement in illegal trafficking;

7. Calls on the Commission to submit a proposal for a directive on foodstuffs which are frequently situated on the border

between dietary and medicinal products. Such legislation should help guarantee good manufacturing practice with a view to consumer protection without restricting freedom of access or choice and ensure the freedom of all practitioners to recommend such products; calls on the Commission to remove trade barriers between Member States by giving manufacturers of health products free access to all the markets in the EU;

8. Instructs its President to forward this resolution to the Council, the Member States, the Commission and the Council of Europe.

B

EXPLANATORY STATEMENT

1. Introduction

Opinion polls in various Member States of the European Union indicate (as if it was necessary) the growing interest of European citizens in non-conventional forms of medicine[4]. In countries for which statistics are available, non-conventional medicine is used by 20 to 50% of the population.

This growing interest is due to a certain disaffection with conventional medicine, where extraordinary technological developments have led to undeniable success at medical level, but at the same time, to an imbalance in the doctor/patient relationship. Moreover, the arsenal of medical products on which conventional medicine is based is certainly effective, but it attacks symptoms above all, and often has undesirable side effects or even causes serious dependence.

There is a growing trend to seek out medicine with a more human face, medicine which deals with human beings and not just their pathologies. Hence the revival of interest in traditional therapies and milder medical remedies which seek not so much to destroy pathogens as to restore the human body's capacity to resist them.

This does not, however, mean that conventional and non-conventional medicine are mutually exclusive. On the contrary, they can function in a complementary fashion to the great benefit of patients.

There are many, many forms of non-conventional medicine; we cannot name them all here. They do, however, have one thing in common - they are either not recognized or only recognized in certain ways by the medical authorities, even if in recent years there have, on the one hand, been attempts to question the irrational scientific prejudice which has attached itself to them, and, on the other, doctors have been proposing practical experiments to their patients with regard to complementary treatment.

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[4]By non-conventional medicine, we mean not the the notions of alternative and/or complementary medicine which are used in the context of conventional medicine (e.g. the term 'alternative' is frequently used when describing a medical treatment which can be used instead of surgery treatment and vice versa) but medical disciplines or practices such as anthroposophy, homeopathy, Chinese medicine or naturopathy, which are full blown medical systems based on theoretical and/or philosophical concepts, and view illness as being less the result of the action of external agents than the imbalance of the organism itself.

2.Legislation in the Member States of the European Union

With regard to health care, two diametrically opposed concepts currently coexist within the European Union. The first believes that only the medical profession (doctors) is entitled to practice health care and treat illnesses, with an exception being made for certain professions which are allowed to carry out certain specific medical or paramedical activities. These specific cases apart, it is illegal to practice medicine. This is the approach taken in the southern countries and France, Belgium and Luxembourg.

That said, the de facto existence of the practice of non-conventional medicine in those same countries, coupled with growing demand from patients, has led to a certain degree of tolerance, e.g. in France, where acupuncture, recognized by the Académie de Médicine since 1950, may be legally practised by medical doctors; moreover, homeopathic remedies are reimbursed by the social security when medically prescribed.

The second attitude, which predominates in the countries of the north of Europe, takes the opposite approach: anyone who wishes to practice health care may do so, but certain activities are strictly reserved for doctors who, moreover, are those who constitute the authorities and the point of reference with regard to organizing health care and health policy.

In the United Kingdom and Ireland, by virtue of common law, any unqualified person, i.e. non-doctor, may practice as a therapist as long as they do not claim to be a medical doctor. This situation has the enormous disadvantage that the fact that neither training nor degrees are legally recognized protects neither serious, competent practitioners nor patients against poorly qualified individuals or even charlatans. This gap was filled in the UK by the 1993 Osteopaths Act and the 1994 Chiropractors Act.

In the Netherlands, a law on Professions in the Individual Health Care Sector (BIG - Beroepen in de Individuele Gezondheidszorg) was adopted in November 1993. In principle, it authorizes anyone to practice medicine, but it does list 'reserved activities', i.e. those which can be carried out only by authorized practitioners. Moreover, this law attaches penal provisions to the freedom to practice medicine: it is punishable to damage patients' health.

In Germany, the freedom to practice health care has existed since 1873, and the professional of 'Heilpraktiker' (health practitioner) has been recognized since 1939; even if no specific training is demanded, practitioners must submit to an examination on their basic medical skills and be entered on the profession's register[5]. Moreover, both homeopathic and anthroposophic medical

[5]Heilpraktiker may, if they have the requisite Erlaubnis (permit) practice non-conventional medical disciplines.

remedies are included in the national pharmacopoeia (with representatives of the discipline concerned sitting on a specific committee, set up in 1978).

Finally, in Denmark and Sweden, non-doctors and paramedics may practise non-conventional medicine within certain limits laid down by the laws of 14 May 1970 and No. 409 of 1960 respectively. Moreover, chiropractic is legally recognized as a health care profession in Denmark (Law No. 415 of 6 June 1991), in Sweden (Law No. 1988/89 : 96) and in Finland.

3. Community legislation

The lack of any homogeneity as regards attitudes and legislation amongst the Member States means unequal treatment for European citizens. Health practitioners recognized in one country may find themselves in court in another Member State for practising medicine illegally. This is contrary to the principles set out in the Treaty of Rome, particularly freedom of movement of persons and freedom of establishment (Title III, Articles 52 to 66 of the Treaty).

While there have been several directives since 1975 concerning the medical and paramedical professions, this is not the case for non-conventional medicine, except indirectly, via the adoption of Directive 92/73/EEC concerning homeopathic medicinal products.

We may quite legitimately conclude that the interests of the pharmaceutical industry have prevailed over those of European citizens. How else can we explain the fact that we have not yet succeeded in establishing a specific methodology for clinical trials of homeopathic medical products, while conventional methodology has been recognized without any adaptation? How else can we explain the fact that Regulation 2309/93 establishing a European Agency for the Evaluation of Medical Products does not include homeopathic, anthroposophic or phytotherapeutic products in its decentralized licensing procedures?

In view of this lacuna, Parliament has no choice but to call on the Commission to take the steps necessary to achieve 'coordination of the conditions for the exercise of the medical and allied professions', to use the wording of Article 57(3) of the Treaty. This does not mean that conditions for practising non-conventional medicine should be standardized, but that all practitioners should be guaranteed the right of establishment, by providing them with the wherewithal to exercise their profession, while fully respecting the principle of subsidiarity.

In order to achieve this, it is essential that the status of non-conventional practitioners be legalized and harmonized, that conditions be established as regards training, that the appropriate medical products be included in the European Pharmacopoeia, and that social security bodies cover the

reimbursement of non-conventional health care and medical products.

4. Towards medical pluralism

The objectives are, on the one hand, to respond to the demands of the Treaty on European Union and the legitimate claims of non-conventional medical practitioners, and, on the other, to respond to a growing demand from patients. It is therefore a question of matching supply and demand, on the basis of a principle of double freedom: freedom for patients to choose the medical therapy of their choice, and freedom for practitioners to exercise their profession.

It goes without saying that this double principle involves guaranteeing the patient both safety and quality treatment. For those disciplines which already enjoy some form of legal recognition in one or more Member States and/or some form of professional organization at European level[6] the guarantee as regards safety may be taken as read in so far as one is dealing with competent practitioners. As regards their effectiveness, studies do exist - admittedly not very numerous, but generally conclusive, in so far as we accept that we will not limit assessment of effectiveness on the basis of the methodology and criteria in force in conventional medicine (essentially, clinical trials with a double blind).

Chiropractic is, on this basis, now scientifically recognized as a therapeutic measure, following several studies carried out at the request of the public authorities, particularly the Medical Research Council in the UK, a government-funded body[7].

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[6] Namely homeopathy, phytotherapy, anthroposophic medicine, naturopathy, acupuncture, Chinese traditional medicine, osteopathy and chiropractic.

[7] -Randomised comparison of chiropractic and hospital outpatient treatment for low back pain of mechanical origin - T.W. Meade, Sandra Dyer, Wendy Browne, Joy Townsend, A.O. Frank, The Medical Research Council Epidemiology and Medical Care Unit, Northwick Park Hospital, Harrow, England, published in the British Medical Journal, Volume 300, 2 June 1990.

-Randomised comparison of chiropractic and hospital outpatient treatment for low back pain: results from extended follow-up - T.W. Meade, Sandra Dyer, Wendy Browne, Joy Townsend, A.O. Frank, The Medical Research Council Epidemiology and Medical Care Unit, Northwick Park Hospital, Harrow, England, published in the British Medical Journal, Volume 311, 5 August 1995.

Conclusive proof of the effectiveness of homeopathy[8] is piling up, even if the orthodox scientific community is not yet convinced. We could go on giving examples involving acupuncture, Chinese traditional medicine, osteopathy and many other methods of treatment.

As the Commission itself has said, proof of therapeutic effectiveness 'is not possible using generally recognized scientific methods, or at least arouses serious controversy'[9]. This opening up to medical pluralism has already found concrete expression in the 1994, 1995 and 1996 EC budgets. Budget heading B6-8332 of the 1994 EC budget created a new item, endowed with ECU 1 million, for research into homeopathy; budgetary heading B6-7142, penultimate paragraph, of the 1995 EC budget asked for ECU 3 million for continuing research into the effectiveness of homeopathy, and paragraphs 4 and 5 of budgetary heading B6-7142 of the 1996 budget earmarked ECU 1 million for 'research on the effectiveness of other therapeutic methods such as chiropractic, osteopathy, acupuncture, naturopathy, Chinese medicine, anthroposophic medicine, phytotherapy, etc.'.

Clearly, in order to back-up and legitimize the process of recognizing non-conventional medical disciplines, we need to go further: we need to organize a dialogue between university circles and the experts in each medical discipline and carry out multi-disciplinary research programmes on the basis of jointly established methodologies and appropriate validity criteria. When a patient feels an effect due to a homeopathic medical products or an osteopathic or other technique, direct causality is not necessarily involved. Clinical trials, assessment of the results of treatment and other scientific and academic studies and research are, moreover required in order to analyze both the facts observed and how they relate to each other. The hypothesis is that a homeopathic medical product, osteopathic manipulation or acupuncture produces an effect: this must be demonstrable.

This need to prove the therapeutic effect should not however lead to discriminate against non-conventional disciplines vis-à-vis conventional medicine: numerous medical practices validated by the latter have been so on the basis of the opinions returned by the medical profession, rather than on the basis of rigorous scientific studies. Nonetheless, it is in principle correct to

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[8]-WALACH, H. (1992). Wissenschaftliche Homöopathische Arzneimittelprüfung. Doppelblinde crossover-Studie einer homöopathischen Hochpotenz gegen Placebo. Heidelberg : Haug.
-LINDE K., JONAS W.B., MELCHAT D., WORKU F., WAGNER H., EITEK F. (1994). Human and Experimental Toxicology. In : Critical review and meta-analysis of serial agitated dilutions in experimental toxicology, No. 13, pp. 481-492.
-KLEIGNEN J., KNIPSCHILD P., ter REIT G. (1991). Clinical trials of homeopathy: a meta analysis. In British Medical Journal, No. 302, pp. 316-323.

[9]COM(90) 72 final, p. 3

claim that making a distinction between 'science' and 'non-science' is both reasonable and subject to modification. In so far as a growing number of complete forms of treatment and medical systems are now scientifically validated, they have ceased to be 'unorthodox' and become part of everyday practice, thereby de facto leaving the sphere of 'non-conventional' therapy. In reality, it would be more intelligent to speak not of a pure and simple or rigid division between science and non-science, but a fluctuating range of proofs and acceptability, as we have seen over and over again throughout the history of science.

5.Training practitioners

The quality of non-conventional medical treatment needs to be guaranteed by appropriate training of practitioners, validated by a diploma. Here again, we are not talking about imposing uniformity, because the level of training required for an optimum professional qualification inevitably varies from one discipline to another.

Full-blown medical systems such as homeopathy, anthroposophic medicine, traditional Chinese medicine (TCM) or naturopathy are, in principle, just as extensive and complete in their application as conventional western medicine, even if the pathological and therapeutic fields covered by these different types of medicine cannot be precisely superimposed on one another. A growing number of practitioners of these systems are seeking to complete autonomy as regards diagnosing, treating and taking responsibility for medical cases. In the same way, more and more patients who turn to these therapies do not view their practitioners as specialists treating a particular pain or a particular organ, but as general practitioners whom they have decided to entrust with the care of their health. Although this should not exclude intelligent collaboration with conventional doctors or other complementary medical practitioners, it does require a degree of professional autonomy which involves high levels of responsibility with regard to the patient's wellbeing, and demands training no less rigorous than that currently required for practising conventional western medicine. To this end, courses leading to a full-blown professional qualification in these systems should and could be followed either at university or in private establishments recognized and subsidized by the national authorities. Such courses of study should lead to the awarding of state diplomas or diplomas recognized by the state.

Other disciplines, such as reflexology, aromatherapy, traditional oriental massage, iridology etc., are practised as complements to more all-embracing therapeutic techniques such as traditional western medicine, homeopathy, phytotherapy, naturopathy, etc., or as complements to one another, and the practitioners do not generally envisage operating on a self-contained basis. The diagnoses and areas of responsibility linked with these

techniques should be limited to interpreting symptoms or conditions already identified by general practitioners (whether of conventional medicine or otherwise). It would therefore be inappropriate to demand that such practitioners have a full-blown university training; but there should at least be provision for high-level qualifications.

Finally, there are, and will continue to be for some time, practitioners of homeopathy, phytotherapy, acupuncture and other major medical systems who prefer to view their role as complementary to that of more broadly or better qualified practitioners (often, conventional medical doctors). Such practitioners are not interested in working autonomously; they prefer to leave questions of diagnosis and general patient follow-up to general practitioners, and to direct patients to hospital consultants where necessary. Here too, full blown university-level qualifications would seem to be inappropriate. It is nonetheless clear that the practitioners in question must possess considerable knowledge of the system they are seeking to practise, because otherwise we would see a 'two-tier' system emerging, which would merely confuse patients.

6. Legalizing and harmonizing the status of practitioners

Over and above the high-level training which is required if non-conventional medicine is to be practised in such a way as to provide patients with guarantees of maximum quality, it is essential that, in the same spirit, the professional status of practitioners be codified.

Most non-conventional medical disciplines, particularly those actually named in this report, already possess an organizational structure in most Member States and even at European level, with a code of professional conduct defining the rules to be respected by practising members of the profession, and a register of members of the profession in question. Given that they have no legal status, several professional associations may on occasion coexist within a single Member State, each with its own code of conduct and register; major disparities exist between Member States.

A European initiative, modelled on the initiative which led to the drawing up of the directives on freedom of establishment and freedom to provide services for doctors, nurses, dentists and midwives, should not only harmonize the status of non-conventional medical health professionals within the European Union, but also within the Member States where no legal recognition exists at present. This recognition cannot be defined under the aegis of the conventional medical profession and its national and European representative bodies, in so far as these 'new' medical disciplines have a separate (holistic) and specific (different field of knowledge) approach of their own.

The establishment of committees of experts, on which equal numbers of practitioners of the discipline concerned and members of the conventional medical profession would be represented, seems an adequate response to the need to assess the effectiveness of the therapeutic methods, establish the area of responsibility and the practices to be reserved, and decide on the recognition of the various non-conventional medical or therapeutic disciplines. With regard to internal organization (deontological code, professional register and upgrading of the training of currently operating practitioners), each discipline should be free to take its own measures.

7. ***Extending the scope of social security***

The fact that the non-conventional medical disciplines lack legal status in most Member States means that it is difficult for them to be covered by the existing social security system. Within the European Union, two approaches have emerged in this connection. Firstly, certain disciplines have been partially integrated: homeopathic medical products in France are reimbursed by the social security, although homeopathy as such enjoys no legal recognition and services provided by homeopaths are not reimbursed on a differentiated tariff scale. The second approach, which is much more prevalent, involves private insurance companies agreeing to set up a parallel reimbursement structure.

Neither of these approaches can be long term: the first, because it is inconsistent, and the second because if it became general, it would form part of a trend towards privatizing social security which would threaten the whole way in which our society is developing.

Clearly, as soon as a given therapy is recognized as valid, it should be reimbursed by the social security. There will be no freedom of choice for patients with regard to medical treatment, even when non-conventional medical disciplines have been legally recognized, if there is discrimination as regards reimbursement by the social security.

All Europe's social security systems are heavily in the red. This should not, however, justify the exclusion of non-conventional medicine; indeed its preventive role, inter alia, should be taken into account in any global reform of the social security systems which might envisage a reimbursement scheme based on the total foreseeable cost of an illness, and not only on the cost of treatment or medical products.

Any therapist who wants to form part of the system would then have to accept the same obligations, medical insurance scales and monitoring of the appropriateness of treatments and prescriptions. However, such monitoring would be carried out by experts in the profession concerned.

Doctors and non-conventional medical practitioners who do not wish to sign a medical insurance agreement must retain the right not to do so, as long as patients are clearly informed of this fact beforehand. Moreover, we cannot deny the right of patients to sign contracts with private insurance companies with a view to covering non-reimbursed medical costs if they so wish.

8. Incorporating non-conventional medical remedies to the European Pharmacopoeia

The European Pharmacopoeia, as drawn up by the Council of Europe, needs to be opened up to other pharmacopoeiae particularly the medicinal plants used in Chinese medicine.

There is no point whatever in legislating on the status of non-conventional medicine, if practitioners do not have at their disposal the full range of therapeutic products which they deem to be indispensable, all the more so since the proposed high level of training should eliminate any fears as to the risk of faulty prescription of medical products. Directive 65/65/EEC and 75/319/EEC therefore need to be revised. The revision should provide for free movement of all medical products, of whatever nature, as long as they have been recognized by one of the non-conventional medical disciplines, using its own criteria. The revision should also deal with the contents of the labels identifying the raw materials used in manufacturing the medical products. Apart from biological tests, it will be necessary to include macroscopic and chromatographic analyses. Furthermore, an assessment committee comprising, for each Member State, qualified practitioners of the non-conventional medical disciplines, and researchers, representatives of the pharmaceutical producers and of consumers' associations with experience in this field, and Commission representatives, will decide on the quality criteria for the products, and on the effectiveness and safety standards which the monographs published in the European Pharmacopoeia will take as a basis. It will be necessary, in the same way, to amend Regulation 2309/93 establishing a European agency for the evaluation of medical products.

Moreover, new European legislation on food supplements will have to be added to existing legislation ; these are often on the borderline between dietary food products and medical products. The new legislation should make it possible to guarantee higher quality with regard to consumer protection and prevent the current absence of any legislation being used to take manufacturers and/or retailers of these supplements to court on the pretext of practising pharmacy illegally.

However, the Community needs to examine the question of imports from third countries where different legislation covers the same products. We need to be able to demand that importers display transparency with regard to the nature and quality of the ingredients of any special product, lacking which, the Community

should ban import of products coming from countries which refuse to apply essential quality and specification standards.

9.Insuring a smooth transition

Clearly, harmonization cannot be carried out from one day to the next. It is also going to be necessary to decide on a moratorium which will allow current legal proceedings against practitioners of the non-conventional medical disciplines mentioned in this report, which are currently under way in certain Member States (notably France), to be suspended. Moreover, we cannot 'evict' all those who hitherto have trained and are practising. An 'equivalence commission' therefore needs to be set up, comprising experts in the discipline concerned and academically qualified teachers, who will examine the situation of those concerned and their diplomas on a case-by-case basis, and decide on any upgrading required.

MOTION FOR A RESOLUTION tabled pursuant to Rule 45 of the Rules of Procedure by the members PIMENTA, DELL'ALBA, DIEZ DE RIVERA ICAZA, CROWLEY, EWING, GONZALEZ ALVAREZ, the Lord PLUMB on complementary (or non conventional) medicine

The European Parliament,

A. whereas a considerable proportion of the population (18 - 75 % depending on the country) has access to complementary methods of treatment,

B. whereas steps should be taken to guarantee patients free access to the treatment of their choice, with all appropriate guarantees,

C. whereas European legislation on the legal basis exercise of complementary medicine will provide one of these guarantees,

D. whereas the free choice of treatment can, alongside other possibilities, be covered by the social security systems which would show no discrimination in reimbursing for services and medicinal products connected with complementary medicine,

E. whereas, in order to guarantee people's right of establishment, restrictions must be abolished, as is provided for in Article 57(3) of the Treaty by coordinating the conditions for exercise of the medical and allied and pharmaceutical professions in the various Member States,

1. calls on the Commission to take measures required to harmonize the statutes of the various disciplines in complementary medicine;

2. calls on the Council to enact legislation on the subject in order to guarantee patients free choice of treatment with all the appropriate guarantees and to guarantee practitioners the right of establishment in an effective manner;

3. calls on the Council to forward a recommandation to Member States to include complementary medicine in the social security systems.

OPINION

(Rule 147)

for the Committee on the Environment, Public Health and Consumer Protection

on the status of non-conventional medicine

Committee on Legal Affairs and Citizens' Rights

Draftsman: Mr Siegbert Alber

PROCEDURE

At its meeting of 29 October 1996 the Committee on Legal Affairs and Citizens' Rights appointed Mr Siegbert Alber draftsman.

It held an exchange of views at its meeting of 25 and 26 November 1996, considered the draft opinion at its meeting of 27-28 January 1997 and at that meeting it adopted the conclusions as a whole by 13 votes to 1, with no abstentions.

The following were present for the vote: De Clercq, chairman; Alber, draftsman; Añoveros Trias de Bes, Berger, Cassidy, Cot, Crawley, Gebhardt, Herman, (for Ferri), Hory, David Martin, Thors, Ullmann, Valverde López, (for Palacio Vallelersundi) and Zimmermann.

The Lannoye report seeks to achieve recognition of non-conventional medicine. It calls for directives, to be enacted in particular for seven named methods of treatment.

I.General considerations

1.Community competence and legal basis

The cross-border dimension of non-conventional medicinal disciplines concerns freedom of establishment for non-conventional medical practitioners and their freedom to provide services, trade in goods (especially medicinal products) and the movement of patients seeking services (patients go to a doctor; the right to choose one's doctor across borders).

The EC Treaty refers to health in Articles 3(o) and (s)[10], 36, 56, 100a(3) and 129. While Community legislation is not provided for in Article 129, it can nonetheless be concluded from the repeated references to health that health protection is a matter for the Union.

[10]Consumer protection; this may relate to medicinal products.

Leaving aside Article 235, Articles 54(2), 57(1) and (2), 63(2) and 100a[11] come into consideration where the legal basis is concerned.

Article 57 appears to provide the most appropriate legal basis in the systematic context, owing to the specificity of its paragraph 3 ('medical and allied ... professions'). Paragraph 1 covers the mutual recognition of diplomas and paragraph 2 the taking-up and pursuit of activities as self-employed persons. The wording of paragraph 1 is kept general, so that diplomas relating to non-conventional medicine which already exist in the Member States can be subsumed under it. The wording of paragraph 2 is likewise general. There are no grounds for arguing that activities in the field of non-conventional medicine should be excluded from these provisions.

Since the articles under consideration are not worded narrowly, it can be assumed that the institutions involved in the legislative process have broad discretion regarding the question of the legal basis.

For the reasons set out below, the powers of harmonization under Article 57(2) are not limited to existing provisions laid down by law, regulation or administrative action. First, the wording of Article 57(2) makes no distinction between existing and future provisions laid down by law, regulations or administrative action. Secondly, the complete absence of provisions can be interpreted, depending on the regulatory context, either as a total ban on or as a total liberalization of the non-conventional medicine concerned. These provisions can then be harmonized anyway. Thirdly, there is a teleological argument against a narrow interpretation of Article 57(2): it would be absurd to wait for sufficient divergence between national rules and only then restore the desired uniformity!

2.Subsidiarity

It should be noted first that there is a huge disparity between the Member States' rules concerning non-conventional medicine. This means that the competitive conditions for non-conventional medical practitioners in the Member States are nowhere near being the same. From this point of view, there is basically a need for action at European level. No European rules are needed, on the other hand, where intervention in the organization and contribution and reimbursement

[11]Directive 92/73/EEC (OJ L 297, 13.10.1992, p. 8) was based on Article 100a.

arrangements of the Member States' health insurance funds is concerned; in accordance with the principle of subsidiarity, such rules remain a matter for the Member States.

3.Abstract definition or closed list?

The definitions proposed by Mr Lannoye should be supplemented as follows:

The concept of non-conventional medicine should be taken to mean those treatments which do not or do not yet form part of conventional medicine, which are highly likely to bring about the promised healing and the provision of which does not necessarily depend on the practitioner holding a State-awarded degree in medical science (doctor's diploma).

An abstract definition is preferable to a list of disciplines, because limiting or even prohibiting new developments in the field of non-conventional medicine would be unjustified.

Moreover, individual directives for each non-conventional medical discipline would serve no useful purpose. A unified directive, like that applicable to conventional medicine, is preferable.

The non-existence of a career profile for an occupation in a Member State should not prevent the pursuit of that occupation in that Member State if it is covered by a European directive.

4.Use of committees

The use of the committees called for by Mr Lannoye basically makes sense, but they must remain within the limits of the Council Decision of 13 July 1987[12]. An administrative committee (Type IIb) is also called for in the Fontaine report (A4-0269/96) on the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications.

5.Protection of patients

The protection of patients is an important aspect of effective health protection. It can be achieved by means of the highest possible qualifications, requirements regarding the provision of information and appropriate compensation mechanisms.

5.1. The level of qualifications for non-conventional medical practitioners

(a) Conventional medical practitioners who have turned to a non-conventional discipline possess the knowledge enabling them to take conventional therapeutic measures if the need arises. Such a level of qualifications is to be welcomed, and this group generates the fewest doubts. Trained doctors who focus on non-conventional medicine may therefore freely work as non-conventional practitioners.

(b) Non-conventional practitioners without a doctor's diploma frequently do not acquire the requisite basic knowledge from their training. The objective should therefore be to secure the highest possible level of qualifications. This can be ensured by means of professional self-regulation: professional bodies could supervise access to and the practice of the discipline concerned. Provided that the members of the profession were sufficiently honourable, they would be the most appropriate people to judge their colleagues. It can be assumed that the professions will apply strict standards in order to limit competition. Such professional bodies should be open to scrutiny by public authorities. The minimum level of qualifications required should be that which has developed in one Member State for the profession of 'Heilpraktiker' (health practitioner). It

[12]OJ L 197, 18.7.1987, p. 33.

must be made absolutely clear that this level of qualifications is not defined in abstract terms, but may be deemed by the relevant authorities, operating with broad discretion, to have been reached or not to have been reached in individual cases[13]. In any event, non-conventional medical practitioners must be required to have basic knowledge of conventional medicine combined with detailed knowledge in the field of the non-conventional discipline concerned.

5.2. Preventive mechanisms and compensation mechanisms

The possibilities here, in the interests of patient protection, are, in the first case, primarily the requirement to provide information and, in the second case, compulsory liability insurance. Practitioners providing treatment should be required to furnish information which is as comprehensive as possible. Information campaigns may also make a positive contribution. The content of the information should be determined and checked by the professional organizations. Compulsory liability insurance should be linked to compulsory membership of the relevant professional organization. It should be up to the same standard as liability insurance for conventional medical practitioners.

[13]Law on the professional practice of medicine without a medical licence (Law on Health Practitioners) of 17 February 1939 (RGBl I, p. 251; BGBl III 2122-2); first implementing regulation on the Law on the professional practice of medicine without a medical licence (Law on Health Practitioners) of 18 February 1939 (RGBl I p. 259; BGBl III 2122-2-1); see Article 1 of the Law on Health Practitioners and Articles 3(1), (2) and 4 of the implementing regulation. Private colleges are available to provide training as a health practitioner, but attendance at them is not compulsory. Local public health departments check the knowledge and skills of health practitioner candidates, on the basis of 'guidelines', before a permit to practise as a health practitioner is granted. Health practitioners are organized in several associations governed by private law.

II.Legal conclusions and proposed amendments

A.Conclusions

1.Non-conventional medical disciplines should be defined in abstract terms. The concept of non-conventional medicine should be taken to mean those treatments which do not or do not yet form part of conventional medicine, which are highly likely to bring about the promised healing and the provision of which does not necessarily depend on the practitioner holding a State-awarded degree in medical science (doctor's diploma).

2.The existence of Community competence in the sphere of non-conventional medicine should basically be affirmed. Rules in this area can be based, in particular, on Article 57(1) and (2). To this end, there should be an explicit reference in the text of the resolution to Article 138b(2) of the Treaty.

3.Any Community system of rules must aim first and foremost to ensure that patients have freedom in their choice of treatment, that they are fully informed about the advantages, limitations and risks of opting for non-conventional medicine, and that they are protected against charlatans.

4.Non-conventional medical practitioners must have the highest possible level of qualifications. The level to be required should be at least equivalent, for example, to that which has developed for 'Heilpraktiker' (health practitioners).

5.Preventive and compensation mechanisms should generally take the form of compulsory membership of professional organizations which are open to scrutiny by public authorities, and in particular the provision of comprehensive information and compulsory liability insurance to be taken out by practitioners carrying out non-conventional treatments.

B.The points indicated below should be changed in the Lannoye report

6.A comment must be appended to the reference, in the second citation of the draft report, to the motion for a resolution of the Parliamentary Assembly of the Council of Europe of 28 January 1994, to the effect that the text in question merely expresses the views of those who signed the motion, and does not constitute an opinion adopted by the Parliamentary Assembly.The second citation should accordingly be deleted.

7.The passage 'whereas the obligations which the Treaty places on the Member States, and specifically those provided for under Article 57(3), urge the Member States to coordinate the conditions for exercising medical and allied and pharmaceutical professions' (recital F, final part) should be deleted, since there is no obligation stemming from Article 57(3).

8.The reimbursement of treatment costs by social security schemes is not a Community matter. Recital L should therefore be amended accordingly

9.Separate directives on the individual non-conventional medical disciplines may not be desirable. The Commission, in collaboration with experts in the various disciplines, should assess whether legislation in this field should not rather be introduced as a unified directive.

10.The passage concerning the bringing of proceedings for failure to act (paragraph 2 of the draft report) is untenable in the light of the wording of the second paragraph of Article 175, and should therefore be deleted.

11.Committees, as proposed in paragraph 6 of the draft report, may only be established by binding legislation. Such legislation must have a legal basis in the Treaty.The equal representation of the conventional and non-conventional sectors on the committee of experts referred to in

paragraph 6 a, and the principle of self-regulation for the assessment committee referred to in paragraph 6 b, do not provide the necessary guarantees for the protection of patients. These provisions should therefore be deleted

12. The moratorium called for in paragraph 7 of the draft report is legally dubious and an infringement of national criminal jurisdiction. All passages in the Lannoye report's resolution directed to that end should therefore be deleted.