

Integrating homoeopathy in health systems

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Homoeopathy is a therapy which involves many components and three main agents: the patient, with his or her condition and personal characteristics; the medication used, with its composition and manufacturing procedure; and the physician, with his or her approach to treatment and concepts of health. The development of research and evaluation structures, combined with a critical education in the discipline, would help to improve practices and define homoeopathy's potential role in relation to the other therapies, both conventional and unconventional, used in Western health systems.

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Homoeopathy celebrated the 200th anniversary of its existence in 1996. On that occasion Germany's Health Minister, Horst Seehofer, stated that its success could not "be denied, even though this has often been attempted", and that "homoeopathic products should always be able to prove their efficacy" (1). At a congress of the International Homeopathic Medical Organization in 1994, WHO's Medical Officer for Traditional Medicines, Dr X. Zhang, referred to the integration of homoeopathy into the national health systems of numerous countries such as Germany, India, Mexico, Pakistan, Sri Lanka, and the United Kingdom (2). She described its characteristics as approaching the patient holistically, prescribing medication that stimulates the spontaneous defence mechanism of the body, and using a minimum dose of the active agent. On the latter point, Dr Zhang noted: "There is no doubt about the safety of homoeopathy because the medical substances have been extremely diluted in homoeopathy drugs. Yet there is still great concern about the clinical efficacy. The mechanism of homoeopathy has not yet been verified in modern medical terms."

The situation reported is one often observed during exchanges between homoeopathic organizations and national and international health authorities: the keen interest in homoeopathy shown by the general public in many countries, the abiding inadequacy of research findings, and expectations of progress from international cooperative efforts.

Historical background and definition

The relations between homoeopathy and Western medical systems are complex. The latter can be characterized as a mechanistic and physiopathological approach to pharmacology based on chemicals or plants and one that is biological and clinically

experimental. To understand these relations we should go back to 1796, when Hahnemann published his *Essay on a new principle for discovering the curative virtues of medicinal substances*, which laid the foundations of the therapeutic approach that was to take the name homoeopathy (3). After describing the theoretical concepts underlying treatment practices of his time, he introduced the basic ideas of the new curative technique: a treatment approach specific to each and every form taken by a condition, the double and inverse effect of medicaments, and therapeutic action due to the similarity of symptoms between those of the artificial condition they induce and those of the "natural" condition observed in the patient. To arrive at a practical application of the symptomatology inherent in each medicament, Hahnemann, his disciples and successors went on to use three sources of information:

- experimentation on healthy individuals with subtoxic doses initially, followed by very weak doses;
- the toxicological and pharmacological knowledge of the period;
- the results of therapeutic observations.

That pharmacological approach, though original, did not lead to a break with the orthodox medicine and pharmacology of the times, and there were many who followed Trousseau in recognizing that the homoeopathic medical discipline formed thereby contained "highly valuable approaches to the special properties of drugs", though it was not free from "systematic illusions" in its experimental work. It had therefore all the interest of a precise semiology but was also dogged by the problem of how to sift through myriads of symptoms of often dubious origin. This is a fair assessment, and many modern practitioners would agree with it.

The difficulty does not arise in the concept of similarity as applied to therapy, a concept which effectively describes "the medicine of similars". Hahnemann admittedly was far too dogmatic about the concept when he made *Similia similibus curantur* a universal law. We feel that the subjunctive *curantur* he

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also used on occasion (3) is more suited to what is in fact a working hypothesis for pharmacology, and can be expressed in numerous ways that are entirely compatible with the contemporary biological approach, particularly for immunology and allergology.

The main difficulty arose later and was related to the mode of preparation of homoeopathic products and the doses used (even today a homoeopathic drug is not defined by indications for use and its place in a class of treatment but by its mode of preparation). It evolved gradually as Hahnemann began to diminish doses to avoid adverse reactions to certain medications (such as mercury salts and toxic plants). It took shape when, 20 years after his founding statement, he defined the mode of preparation in successive dilutions calculated in parts per cent, recommending the use of high dilutions. It became clear when in the theoretical work of his declining years, Hahnemann described the dilution process as a type of "dynamization" permitting non-material medicinal virtues to be obtained by acting on the "vital principle".

Paradoxically, this difficulty also helped homoeopathy to open up in two ways (4): culturally in countries such as India where belief systems offered philosophical parallels with homoeopathy; and scientifically in the search for the mechanisms of physico-chemical actions which led to a considerable amount of serious and interesting research work, as well as numerous theories, often poorly supported and sometimes publicized too much and prematurely. The controversy over "the memory of water" is a good example of these cases, where often insignificant details are more highly publicized than the scientific ones that are worth in-depth and sophisticated analysis.

In the last phase of his life (3), Hahnemann expanded the basic principles of homoeopathy in a treatise on chronic diseases, in which he described the diatheses underlying chronicity, and the succession and alternating states of different pathological episodes. In homoeopathic practice, these diatheses can either turn into intangible dogmas with homoeopaths trying to graft them onto outdated concepts, or they can become interesting points of reference for everyday clinical practice providing a more precise idea of the patients' background and assisting efforts to improve their state of health in the longer term.

A better definition of homoeopathy is contained in the title of a reference work: *Homéopathie, médecine de l'expérience* (5) — "the medicine of experiment" [and experience]. It is experiment that brings together a precise semiology whose validity must be tested, a holistic view of each patient and an empirical approach to their background, and a method of prescribing medication from which all toxicity has been attenuated, which in turn raises the question of whether its active principle is scientifically based. To this may be added the question of how to make it fit different cultures, which has given

rise to great variety in the mode of prescription. Nowadays the "system spirit" only concerns those who are still attached to the original dogmas of homoeopathy, forgetting that throughout his life the founder of homoeopathy kept developing his theories and refining his practices.

Homoeopathy and its links with present-day health systems

It is impossible to provide an exhaustive overview of all these activities. We will try to illustrate them through representative samples of the interaction between homoeopathy and health systems: in France, where education, basic research and evaluation have been a focus for various types of activity in the last few years; in Europe, where a report on alternative medicine has recently been submitted to the European Parliament; in the United States, where an Office for Unconventional Medicines has been established at the National Institutes of Health; and in Brazil, where homoeopathy is a recognized medical speciality.

Homoeopathy and the French health system

Homoeopathy in France is in a paradoxical position. Homoeopathic remedies are found in the French pharmacopeia, are generally reimbursed by the French social security system, are available from all pharmacy outlets, and are produced industrially in accordance with a guide to good manufacturing practices issued in 1992. Two of the laboratories concerned are among the world leaders in the homoeopathic remedies market. This situation reflects the popularity of homoeopathy: a survey conducted in 1992 by IFOP, an agency that does research on French public opinion, showed that 36% of the French public were regular or occasional users, and a series of other surveys have shown that 60% of all French people are in favour of using it (4). However, the institutional situation of homoeopathic physicians is still precarious; they do not enjoy proper status in the hospital or the medical school system, they are almost exclusively in private practice, teaching is also mainly private, and there is no official recognition of this "treatment approach" by the self-regulating body of the French medical profession, the Conseil de l'Ordre des Médecins.

Present trends in matters relating to clinical research, basic research and education and training show the steps taken to try and change the situation.

Clinical research. Dr Michel Aubin, France's pioneer of institutional activities in controlled homoeopathy trials, held negotiations on the subject of clinical research with the Directorate of Medical Drugs and Pharmacy in 1983. In 1984, he informed the Directorate that a working group on controlled homoeopathy testing had been formed under the Syndicat national des Médecins homéopathes (the

national union of homoeopathic physicians). The aim was to draft protocols that respected both conventional methodology and homoeopathic rules. This happened in 1985 when the Social Affairs Minister, Georgina Dufoix, set up a ministerial commission on the subject, composed of members of the national research institute, INSERM, and two homoeopathic doctors. The commission was called the "homoeopathy research and clinical trials group", with the acronym GRECHO, and it decided on two types of approach.

- The first, in the short term, was to rerun an already published trial: the effect of opium and raphania in the resumption of passage through the intestine after laparotomy. It was chosen as it had already been the subject of two preliminary trials showing a difference in effect between homoeopathy and a placebo. It was not representative of homoeopathic treatment, however, and though the GRECHO commission agreed to it, it expressed reservations about the general applicability of the results.
- The other, a medium-term activity, was to help improve evaluation of the effects of individually prescribed homoeopathic treatment. The two fields chosen were the treatment of infections in the upper respiratory tract of children, and preventive treatment of herpes labialis.

In the event, only the first trial, on opium-raphania, was performed, as the funds for the other trials were withdrawn in 1986. In March 1988, the results of the trial were published in *The Lancet*, showing that neither opium 15 CH nor raphania 5 CH had any impact on the resumption of passage through the intestine among patients recovering from interventions in the digestive tract. In the light of these results, *Le Monde* published an article with the headline "Homoeopathy ineffective" which gave rise to lively debate.

Research and education. At the same time a better balanced analysis was made by a scientific observer from the journal *La Recherche*, who contacted me as a member of GRECHO:

"Do the negative findings from the study mean we should declare homoeopathy to be generally inefficacious? The members of this research team, whether homoeopaths or not, are still careful to stress that their results cannot be extended to cover every area of homoeopathy... So far as the precepts of homoeopathy are concerned, the "individuality" of every patient has not been taken into account. In actual fact, Dr B. Poitevin, who recently submitted to the Ministry of Health a general evaluation of homoeopathy, considers that three studies are not enough, no matter how strict they might have been, but for a truly objective evaluation of homoeopathy, perhaps 30 studies might be required. Above all, the research teams would have to be free to work in total independence, free from the vagaries of political change. But, given the unfavourable result announced by GRECHO, it

is very unlikely that such an experiment will be repeated. This fact is regrettable particularly in view of the fact that France is the country in which the largest number of patients have recourse to homoeopathy" (6).

A second ministerial commission was concerned with education and training. All the homoeopathy schools had developed an education and training programme designed to lead to an inter-university degree in homoeopathy. Such a qualification has been instituted for acupuncture but not for homoeopathy. For the last two years at the behest of the executive board of the National Association of French Homoeopathic Physicians, a commission including members of the Council of French physicians, university staff and homoeopathic physicians has been working to develop an inter-university degree. The commission's report has been discussed by the Council of Physicians, which recommended that a degree should be instituted. A consensus emerged during the work of the commission on evaluation activities, which should be increased in France by being based on the universities.

Evaluation. General reviews of clinical trials of homoeopathic treatment published in the international literature have been carried out, with varying conclusions on how to go about future testing. Thus, two French researchers say "The large-scale randomized trials required for evaluation of possible effects of homoeopathy may imply costs out of proportion to their usefulness"(7). In their opinion, such trials are unlikely to modify significantly the views already held by either physicians or by patients, but they do not present arguments for this opinion.

Three Dutch epidemiologists who wrote a very comprehensive review (8) evaluating 107 controlled homoeopathy trials noted that 15 of the 22 "best studies" had proved positive. Further controlled trials are, they feel, essential. "Additional proofs must, in our view, consist of a few well-performed controlled trials in humans, with a large number of participants under rigorous double-blind conditions. The results of the trials published so far and the large scale on which homoeopathy is practised, makes such efforts legitimate." Similar recommendations have also recently been made by the European working group (see below). It is essential to evaluate the effects of homoeopathy in different selected pathological conditions but this calls for resources and structures which are not at present available to the homoeopathic medical community in France. Fortunately, the situation is different in the rest of Europe and the United States.

Literature evaluating homoeopathy also includes other scientific work (9), chiefly in biology. These trials, which cannot be reduced to efforts to test "the memory of water", are written about regularly in reference publications. This helps broaden the experimental discussion on the effect

of very high dilutions and the biological targeting of certain homeopathic medications.

Homeopathy and Europe

Recently a report on complementary medicines was submitted to the European Parliament. The Standing Committee of European Practitioners, of which the French Order of Physicians is a member, expressed its opposition to the report, recalling that medical intervention presupposes diagnosis before treatment and stating that only medical education could meet that requirement (10). In the same context, the Standing Committee said "it seems unthinkable to promote untested practices when even the experts who use them concede that they do not lend themselves to evaluation".

The report on the status of non-conventional medicines was finally adopted on 29 May 1997, with some amendments. The relevant resolution called for the European Commission to carry out tests on the safety, utility, field of application and complementarity or alternative nature of every non-conventional school. Concerning the particular case of homeopathy, the position of European practitioners was identical to that of the French physicians regarding the requirement for diagnostics in which quality is ensured by medical education. However, the theories of those who advocate untested and unassessable practices have nothing in common with those of French and European homeopaths. As the French Order of Physicians knows full well, the homeopathic physicians on the Commission are all in favour of evaluation. Physicians with seats in the European Parliament are likewise aware of this willingness since it was the Parliament that in December 1993 requested the European Commission to explore the conditions necessary for scientific research on homeopathy.

Following that request, a research group was established under the aegis of the European Commission in September 1994, comprising specialized research homeopaths, clinical and pharmacological research workers, and methodologists. This team of 16 experts marked the bicentenary of homeopathy with a report issued in September 1996 (1,11), which deemed homeopathy to be suitable for submission to evaluation criteria for clinical efficacy while acknowledging that it was a treatment approach consisting of several different components (11). The same group issued other documents, including a reference dictionary and, in particular, a meta-analysis of previous clinical trials. For the overall results of 15 eligible trials, this gave a statistically significant difference in favour of homeopathy, but sensitivity analysis showed that care had to be exercised in advancing the conclusion in view of the relatively poor quality of the tests and trial reports (12). In the words of Dr Peter Fisher, a member of the group, a rheumatologist and Research Director at the Royal London Homeopathic Hospital, homeopaths could not afford to

be complacent and more work needed to be done (12).

Together with Professor Flavio Dantas, Fisher organized a scientific meeting in London in January 1997 to evaluate the results of day-to-day homeopathic practices. To improve the quality of homeopathic practice the first thing to do is to assess the reliability of findings on medical topics. Dantas has undertaken a rigorous analysis of the sources of homeopathic semiology (13), concluding, 200 years after Trousseau, that the medicinal effects of homeopathy had been overestimated on the basis of experiments on healthy subjects. This has led to an accumulation of unreliable data and unsuitable prescriptions. It has been observed that the critical dynamism of the London homeopaths is related to their advantage in having a homeopathic hospital with royal patronage, in which homeopathy is practised, evaluated and taught.

In Europe, therefore, the desire to evaluate the clinical efficacy of homeopathy is clear. There are limitations to it, however, of the following three types:

- the wide range of modes of prescribing homeopathic medication, depending on the school;
- ignorance of the mechanisms governing the action of high dilutions, as a result of which such important factors as the pharmacokinetics of drugs and the duration of their efficacy are unknown;
- the small number of hospitals employing homeopathic medical practitioners; the Royal London Homeopathic Hospital is one of the rare exceptions in Europe, and has produced a document outlining advances in research on alternative medicines in an effort to incorporate them in a system of medical practice based on factual evidence.

Homeopathy in the Americas: the United States and Brazil

After major progress in the 19th century that peaked around 1900, homeopathy in the USA became far too closely intertwined with vitalist theories, and proved unable to keep up with scientific developments in medicine (4,5). Unlike the experience of France, in which homeopathic practitioners maintained a strong clinical tradition (5), the drift into esoterism resulted in its marginalization. Matters took a new turn in 1993, however, with the establishment of an Office for the Study of Unconventional Medical Practices under the National Institutes of Health. Work is at present under way at the Research Center for Alternative Medicine (Beth Israel Hospital and Harvard Medical School), in collaboration with the European Commission's Homeopathy Research Group. The Office for Alternative Medicines, where homeopathy is only one of several areas of interest, takes an experimental approach (clinical and biological trials), but includes economic, sociological, philosophical and spiritual factors that come into play

when patients and practitioners alike choose alternative therapies.

In Brazil, where the present-day structure of the medical system is based on the American model, homoeopathy has been a speciality recognized by the medical authorities since 1992. It forms part of public and community health programmes of different states of Brazil. Every other year an international symposium for institutional research on homoeopathy discusses all aspects of its development, from sociological issues to basic research, and evaluates homoeopathic practices. Among the different university centres, medical associations and dispensaries we visited in Brazil, three in particular have had a very beneficial effect on integrating homoeopathy into the country's health system:

- the Hahnemann Institute of Brazil (Rio de Janeiro) whose teaching and outpatient dispensary structure enables comparative studies of various homoeopathy practices to be made, while making access easy for poor population groups from the surrounding *favelas*;
- the Paulist Association (São Paulo), whose work is very well integrated with the São Paulo State and City's public health system;
- the Federal University of Uberlândia, where Professor Dantas, former Dean of the Faculty, who teaches both medical ethics and homoeopathic therapeutics, has begun to introduce students to homoeopathy research and critical evaluation of the literature.

Proposals for closer incorporation of homoeopathy into Western medical systems

From a cursory glance at the characteristics of homoeopathic "medicine" independently of its dogmas and its relation to different Western health systems, we can make the following proposals for evaluating treatment procedures (14), developing education and training in the subject, and improving practice.

- **Find out more about the prevalence, costs and ways of using homoeopathy.** Studies of this kind have been performed on all non-conventional medical systems in the United States (15) and Australia (16), where specialists see it as a public health responsibility to find out how much the benefits derived from alternative medicines cost.
- **Improve the quality of homoeopathy practice, especially in the following ways:**
 - by developing a better understanding of homoeopathy, especially its semiology; what is needed are new trials on healthy persons, bringing toxicological or allergological findings for certain medications up to date so as to arrive at a better understanding of reliable symptoms;
 - by aiming the prescription of medications not at semiology alone, but also at their physiological effect as a function of composition

and tropism, which has already been initiated in recent medical practice;

- by comparing different types of homoeopathic practice, which is essential for standards of practice to be laid down.
- **Promote clinical research:**
 - by opening up hospital services for homoeopathic clinical practice, so that controlled trials can be carried out based on the realities of its practice;
 - by developing different types of clinical trials depending on the homoeopathic medications tested; proprietary drugs in low dilutions are close to phytotherapy, and perfectly suited to classical methodology; conversely, highly individualized treatment that includes basic medications in high dilutions calls for modifications in the protocols;
 - by incorporating in the studies parameters for the quality of life and economic data.
- **Develop basic research:**
 - by establishing research topics on the physiological mechanisms governing medications; this work, largely performed on the initiative of homoeopathic laboratories, could be conducted in cooperation, for example, with universities and regional authorities, as was the case with a study recently conducted on weak dilutions of *cocculus alkaloids* (17);
 - by reproducing or carrying out physicochemical research, in particular on the spectroscopic characteristics of "highly diluted" solutions (4, 9); the existence of plausible mechanisms of action is a partial key to the acceptability of clinical research results (8); it can also alter cultural attitudes, in particular among those scientists who still consider homoeopathy as just a "molecular absurdity"; if absurd approaches have practical consequences, the paradox is such that they deserve to be scientifically investigated.
- **Develop critical education and training in homoeopathy:**
 - in university education, by providing information to all students, then by instituting an inter-university degree allowing practitioners trained under it to incorporate homoeopathy in a therapeutic strategy after the establishment of a diagnosis;
 - during continuing medical education, by adding the benefits of conventional medical training to those of non-conventional therapies.
- **Maintain the "humanism" of homoeopathic practices:**
 - by making the best use of everything that consultation employs to benefit the patient-doctor relationship, promoting a change in the perception of an illness, and helping the patient to control the state of his or her health;

- by maintaining the Hippocratic tradition, in particular by studying interactions with the environment and by combining the overall and individual approach to the patient: homeopathy is also a “medicine of the person”.

Homeopathy is 200 years old and is one of the most widespread non-conventional approaches to treatment known to the world, along with traditional Chinese medicine, herbal medicine and osteopathy. Homeopathy forms part of our overall common heritage because of its low costs, because prescriptions are safe so long as they form part of a diagnostic approach, and because of the simple technology employed in its preparation, albeit requiring high levels of experience and knowledge.

If homeopathy works, with its triple focus on medication, prescription method and approach to the illness and the patient, it is an inherited good that belongs to all of us equally: the patients who take the medication, the physicians who prescribe it, the pharmaceutical laboratories that manufacture it, the pharmaceutical outlets that issue it, the scientists who are trying to evaluate it, and the health systems that attempt to regulate the costs, advantages and risks of such activities. To argue for an improvement in the relations between homeopathic agencies and Western health systems, chiefly by developing education, training and evaluation, is therefore not illusory or idealistic, but the statement of a complex reality which makes cooperation indispensable. ■

Résumé

Intégration de l'homéopathie dans les systèmes de santé

L'homéopathie a deux siècles et fait partie, avec la médecine traditionnelle chinoise, la phytothérapie et l'ostéopathie, des thérapeutiques non conventionnelles les plus répandues dans le monde. L'intérêt marqué de la population de nombreux pays pour cette thérapeutique contraste avec son intégration, restée très partielle, dans les systèmes de santé des pays occidentaux. Cette réserve des structures officielles repose essentiellement sur des données jugées encore insuffisantes de la recherche, en particulier sur le(s) mécanisme(s) d'action des hautes dilutions. Cependant, cette thérapeutique a des relations réelles avec les systèmes de santé, comme l'illustrent plusieurs exemples représentatifs : en France, où les dossiers de l'enseignement, de la recherche fondamentale et de l'évaluation ont fait l'objet de différentes actions ces dernières années; en Europe, où un rapport sur les médecines alternatives vient d'être remis au Parlement européen; aux Etats-Unis d'Amérique, où un bureau des médecines alternatives a été créé dans le cadre des Instituts nationaux de la Santé; et au Brésil, où l'homéopathie est une spécialité médicale reconnue.

L'homéopathie apparaît aujourd'hui comme une thérapeutique à multiples composantes où intervien-

ent trois acteurs : le patient, sa pathologie et ses caractéristiques personnelles; le médicament, sa composition et son procédé de fabrication; le médecin, ses orientations thérapeutiques et sa conception de la santé. Pour cette «médecine de la personne» dont les valeurs humanistes sont essentielles, l'avenir passe par un refus de toute pensée dogmatique et par une meilleure insertion dans les systèmes de santé. Dans cette perspective sont présentées des propositions relatives à la recherche clinique et fondamentale, à l'évaluation de cette thérapeutique, au développement de son enseignement et à l'amélioration de sa pratique.

La thérapeutique homéopathique, par son faible coût et sa prescription sans danger si elle est effectuée dans le cadre d'une démarche diagnostique, fait partie du patrimoine commun à tous. Le développement de structures de recherche et d'évaluation, joint à un enseignement critique de cette discipline, permettrait d'en améliorer la pratique et de définir la place qu'elle peut occuper à côté des thérapeutiques conventionnelles et non conventionnelles dans les systèmes de santé occidentaux.

Resumen

Integración de la homeopatía en los sistemas de salud

La homeopatía tiene dos siglos de existencia y forma parte de la medicina tradicional china, la fitoterapia y la osteopatía, que son las terapéuticas no tradicionales más extendidas en el mundo. El acentuado interés de la población de muchos países por la homeopatía contrasta con su integración, que sigue siendo muy parcial, en los sistemas de salud de los países occidentales. La reserva de las estructuras oficiales se basa fundamentalmente en la presunta insuficiencia de los datos de investigación, en particular los relativos a los mecanismos de acción de las altas diluciones. Sin embargo, esta terapéutica tiene efectivas relaciones con

los sistemas de salud, como ilustran varios ejemplos representativos: en Francia, en el curso de los últimos años, se han adoptado diferentes medidas en relación con, la enseñanza, la investigación fundamental y la evaluación; en Europa acaba de presentarse al Parlamento un informe sobre las medicinas alternativas; en los Estados Unidos de América se creó una oficina de medicinas alternativas en el ámbito del NIH (institutos nacionales de salud), y en el Brasil la homeopatía es una especialidad médica reconocida.

La homeopatía se considera hoy una terapia de componentes múltiples en la que intervienen tres

actores: el paciente, su patología y sus características personales; el medicamento, su composición y su procedimiento de fabricación; y el médico, sus orientaciones terapéuticas y su concepción de la salud. Para esta «medicina de la persona», cuyos valores humanistas son esenciales en los sistemas de salud, el futuro pasa por un rechazo de todo pensamiento dogmático y por una mejor inserción en los sistemas de salud. Desde esta perspectiva, se presentan propuestas relativas a la investigación clínica y fundamental, a la evaluación de esta terapéutica, al desarrollo de su enseñanza y al mejoramiento de su práctica.

La terapéutica homeopática, por su reducido costo y la ausencia de riesgo en sus prescripciones si se realiza en el marco de un diagnóstico, forma parte del patrimonio común de todos. El desarrollo de estructuras de investigación y evaluación junto con una enseñanza crítica de esta disciplina permitirían mejorar su práctica y definir el lugar que puede ocupar junto a las terapias tradicionales y no tradicionales en los sistemas de salud occidentales.

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