A strategy for research in homeopathy

Assessing the Value of Homeopathy for Health Care in Europe

**PREFACE**

Homeopathy is claimed to be effective by millions of patients and thousands of homeopathic doctors all over the world. However, the effectiveness of homeopathy continues to be debated and its mechanism of action remains poorly understood. The main objective of this report is to provide a strategy for assessing the value of homeopathy for health care in Europe.

The strategy delineated by this report focuses on increasing:

- knowledge of homeopathy
- understanding of its working mechanism
- the effectiveness of homeopathy

In the “Beijing Declaration”, the World Health Organization stated in 2008 that:

“Traditional medicine (including homeopathy) should be further developed based on research and innovation in line with the "Global strategy and plan of action on public health, innovation and intellectual property" adopted at the Sixty-first World Health Assembly in resolution WHA61.21 in 2008. Governments, international organizations and other stakeholders should collaborate in implementing the global strategy and plan of action.”

This WHO decision was ratified in 2009 and aimed “to strengthen cooperation with WHO collaborating centres, research institutions and non-governmental organizations in order to share evidence-based information taking into account the traditions and customs of indigenous peoples and communities; and to support training programmes for national capacity building in the field of traditional medicine.”

There is no doubt that research in homeopathy is meaningful to citizens of Europe and the rest of the world. In fact, consumer surveys show an increasing popularity of non-conventional medicine and especially homeopathy. Both users and critics agree that serious side effects do not occur and that these medicines are safe to take. Because of this safety Council Directive European Directives 2001/83/EC (ex 92/74/EC), 2004/27/EC & 2001/82/EC (ex 92/74/EC), 2004/81/EC permits a simplified registration procedure for most homeopathic medicines. In addition, homeopathic care is inexpensive and therefore promises to provide substantial savings to health service and welfare budgets. Homeopathy’s aim to mobilize the self healing properties of the body in a curative and/or preventive sense is welcomed by European citizens for their personal health care. In addition, if homeopathy is introduced in the livestock farming sector, the European citizen could also be better protected from pharmacological residues in animal products.

In general, homeopathy has the potential to provide a substantial contribution to improving quality of life for European citizens and would thus appear to qualify for research funding by the European Union.

This 2012 report has been drafted and edited by Dr Michel Van Wassenhoven. Taking the 2003
version as a base, the European Committee for Homeopathy (ECH) asked all individuals who were known to be involved in homeopathic research in the European Union for their comments, suggestions and contributions. This final report can therefore be understood as the shared view of all homeopathic researchers in the European Union.

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SUMMARY

The objective of this report is to provide a strategy for assessing the value of homeopathy for health care in Europe.

Homeopathy is becoming increasingly popular in the European Union with millions of consultations taking place each year. Both users and critics agree that serious side effects do not occur and that these medicines are safe to take. Homeopathic care is inexpensive and therefore promises to provide substantial savings to health service and welfare budgets. Homeopathy’s aim of mobilising the self-healing mechanisms of the body in a curative and/or preventive way is welcomed by European citizens for their personal health care. A majority of general practitioners in several European countries believe that homeopathy, like some other forms of complementary medicine, deserves a place in mainstream medical practice. Given this, it is clear that homeopathy should figure more largely in both primary and secondary health care.

Over the 200 years of its existence, a large amount of evidence has been published on the curative effects of homeopathic medicines. Its longevity and widespread use throughout the world (WHO, 2001, 2005, 2008, 2009, 2010 ref. 1-2-3-4-5) bears witness to the essential soundness of the homeopathic approach. The fact that homeopathic medicines are effectively used in veterinary medicine for inflammatory and hormonal disorders is convincing evidence that homeopathy has more than a placebo effect. Further evidence obtained with animals, in isolated organ systems and cell preparations in vitro has been accumulating over the last decade.

Although encouraging results have been obtained in properly performed clinical trials which supported the efficacy of homeopathy, as was shown in several meta-analyses (ref. 6-7-8), homeopathy is still much disputed by mainstream medicine (ref. 9). In order to be accepted as a valid part of medical practice, more research investment is needed. Research in homeopathy has frequently been hampered by problems of plausibility and of scepticism, as well as by gross underinvestment in the academic resources required.

The Homeopathic Medicine Research Group (a joint group of researchers in mainstream medicine and homeopathy formed by the Directorate General XII of the European Commission, ref. 10) concluded that homeopathy is certainly researchable. They advised that further research in homeopathy should be stimulated and produced guidelines for reviewing clinical research protocols in homeopathy, concluding that the highest priority should be given to clinical research, the main thrust of which should be large trials of sound and rigorous methodology. In addition, in fundamental research, there should be repetitions of those model systems previously used in which an effect of high potencies have been demonstrated.

The Action COST B4 (this Action on Unconventional Medicine was established in 1993 and ended in 1999, ref. 11-12). The COST initiative encompasses member states of the European Union and enables wider participation from countries within the Council of Europe. They concluded: “Without the development of a research infrastructure which reflects the actual prevalence and relevance of complementary therapies in health care, an adequate evaluation of this huge field (complementary therapies) is not possible. However, many complementary interventions are already widely used by a large number of physicians and other providers who claim positive experiences. A large number of patients seeks complementary care and perceives
such treatment as effective. At least the most relevant topics should be investigated systematically. A sound evaluation of clinical effectiveness will consume relevant resources. However, if such a trial for evaluation is not undertaken the discussion of complementary therapies will remain dominated mainly by prejudices, inadequate generalizations and uncertainty.” So far as homeopathy is concerned, the report states that, “although overall the available clinical trial evidence suggests that homeopathy can have an effect greater than placebo, this evidence is not (yet?) compelling”.

One of the main objectives of the current report is not only to promote homeopathy by effectiveness studies, but also to improve it by trying to understand and evaluate its therapeutic success (or failure) in daily practice. Apart from efficacy, important questions concerning safety, mechanism of action, the value of different therapeutic strategies and costs need to be investigated in a systematic way.

**Clinical and socio-economic research (ref. 25)**

To assess the effectiveness and efficacy of homeopathy, the ECH takes the view that a step-by-step approach is necessary, beginning with data collection in daily practice and retrospective research aimed at collecting clinical cases, proceeding to open outcome studies, then to randomised clinical trials. The main advantage of this approach is the systematic way in which knowledge is gathered from the population under study.

A programme should be set up for post-marketing safety studies and the evaluation of cost-effectiveness, patient satisfaction and preferences, and effects upon quality of life.

The testing of homeopathic remedies in homeopathic pathogenetic trials or “provings” required methodological improvement; one of the main objectives for research in this field was to establish appropriate standards, and guidelines can be seen at [www.homeopatheurope.org](http://www.homeopatheurope.org) and [www.lmhint.net](http://www.lmhint.net). In addition, new remedies require testing and currently used remedies should also be retested.

In view of rules which are soon to be introduced regarding organic livestock farming, the development and introduction where possible of homeopathy into the livestock farming sector is particularly important. This has the potential both to protect consumers better from pharmacological residues in animal products and to improve conditions for livestock.

**Fundamental research (ref. 25)**

The constraints to the acceptance of homeopathy which are most often cited by opponents are the lack of a scientific basis and the absence of a theoretical model for homeopathy. The large majority (90%) of fundamental research in homeopathy is concentrated on demonstrating an effect of diluted and dynamised (or succussed) agents or remedies. Hardly any research relates to the similia principle (Ref. Wiegant F, Van Wijk R. The similia principle: results obtained in a cellular model system. Homeopathy. 2010 Jan;99(1):3-14. Review.), nor has there been any systematic programme to unravel the underlying mechanism required to explain the action of high potencies. Research activities should therefore be concentrated on the two most fundamental aspects of homeopathy, i.e. the similia principle (remedies or conditions that cause symptoms in healthy biological systems can be used to treat the same symptoms in disease), and the specific way in which remedies are produced (by the process of successive dilution and succession called
Within research on high potencies, two main activities are required:

- repetition of experiments which have yielded positive results in various model systems (ref. 13-14)
- further elaboration of the physical and information aspects involved in potentisation in order to improve our understanding of how potencies maintain their information, how this information interacts with the organism and in what way it can be transmitted to exert its curative action. (There are several suggestive trials. See 1.4. Fundamental research for some references)
1. INTRODUCTION

1.1. Current position of homeopathy

According to various surveys, it is estimated that in Europe at least 20% - 70% of the population has used CAM at least once in their lifetime (ref. 15). New surveys confirm these figures (ref 16). The United Kingdom and the Scandinavian Countries appear to have had rather low use while German population seem to be more prolific users (COST B4 1999, ref. 11-12). Homoeopathy is one of the most used CAMs in Europe: 36% of the French, 32% of the Belgian, 31% of the Dutch, 27% of the Spanish and 20% of the British public have reported taking homoeopathic medicines in recent public opinion surveys; the most recent research indicates that these figures continue to increase (33% for Spain, 36% for Belgium). In Belgium, CAM treatments are a fundamental right for patients (legislation in 2002 concerning patients’ rights). In the United Kingdom the market for homoeopathy is growing continuously; growth is more rapid in some southern countries, while in those with well developed markets (such as France and Germany), the growth rate is slower. The total European market for homoeopathic medicines in 2001 was 1,612 million €, the largest markets being Germany and France, with 36% and 33% respectively of the total market. The European Union has taken steps to create a single European market for homoeopathic medicinal products: EC Council Directives 2001/83/EC (ex 92/74/EC), 2004/27/EC & 2001/82/EC (ex 92/74/EC), 2004/81/EC applying to homoeopathic medicinal products for human and veterinary use are now compulsory in all European countries. The European agencies are now working on harmonised European registration procedures for homeopathic medicines.

Over the past few decades, encouraging results have been obtained in clinical trials, supporting the efficacy of homeopathy as was shown in recent meta-analyses (Kleijnen et al. 1991, ref. 6, Linde et al. 1997, ref. 8, HMRG report 1997, ref. 7, COST B4 report 1998, ref. 11, Reilly et al. 2000, ref. 17). Nevertheless, homeopathy remains much disputed by mainstream medicine (Shang 2005, ref 9) and the debate has reached a crescendo with recent reports by the UK House of Commons Science and Technology Committee (STC), ref. 26, and the Belgian Federal Knowledge Centre for Healthcare (KCE), ref. 16, both of which concluded that there is no proof of its effectiveness (De Gendt et al. 2011; House of Commons, 2010). In fact, these conclusions are based on prior-belief rather than any real audit of the literature (see LMHI Report Reaction on KCE position www.lmhint.net and ref 28-31).

1.2. European Commission Homeopathic Medicine Research Group (ref. 7)

In December 1993 the European Parliament requested the European Commission to conduct a scientific investigation of homoeopathy. Directorate-General XII (Science, Research and Development) of the European Commission supported an expert group, the Homoeopathic Medicine Research Group (HMRG) to conduct this investigation, with the mandate to discuss methodologies, to undertake a constraint analysis, to develop common standards, and to consider whether homoeopathy is a researchable question.

In their report the HRMG concluded that homoeopathy is certainly researchable. They advised the stimulation of further research in homoeopathy and produced guidelines for the review of clinical research protocols in homoeopathy. An overview of clinical research in homoeopathy identified 184 controlled clinical trials of homoeopathy. The statistical meta-analysis of pooled results gave highly significant results in favour of homoeopathy. The HMRG also examined the constraints to the acceptance of homoeopathy by sending a questionnaire to a sample of 1500 decision makers in Austria, Belgium, France, Germany and Great Britain. Despite wide divergence of attitudes to homoeopathy, there was a consensus that more research is required: 77% of supporters and 62% of opponents of homoeopathy favoured more scientific investigation. Two main fields of research in homoeopathy can be identified, namely clinical research and fundamental research. Clinical research is given highest priority by the HMRG with an emphasis on the randomised clinical trial and on improving methodology in order to establish the efficacy of homoeopathy. Their report provides some useful guidelines on methodology for clinical research in homoeopathy “with the objective to allow commonly accepted judgments of clinical efficacy, effectiveness and benefit of homoeopathy by future clinical research”. With respect to fundamental research, the HMRG recommends the replication of previously used model systems in which an effect of high potencies has been claimed.
1.3. Action COST B4 Unconventional Medicines (ref. 11-12)

COST is an initiative of the European Commission which aims to improve pan-European collaboration in science and technology. In June 1993, COST Action B4 in Unconventional Medicine was established. Priorities of this action are to co-ordinate and promote research into the field of Unconventional Medicine and to make information on existing relevant data available to all Signatories. The final report and its supplement were published in 1999. The participating countries in COST Action B4 were Belgium, Croatia, Denmark, Finland, Germany, Hungary, Italy, The Netherlands, Norway, Slovenia, Spain, Sweden, Switzerland, United Kingdom. Since the field of Unconventional Medicine is of medical, social, cultural, psychological, legislative and economic importance, high quality research in all these areas was integrated into the co-operation. In a publication by Vincent & Furnham (1996, ref. 15) it was pointed out that Homeopathy patients were most strongly influenced by the ineffectiveness of orthodox medicine for their complaints. As alternative treatment and remedies tend to be less expensive, a reduction in the costs in the outpatients segment could be expected if alternative treatment is used instead of the classical one rather than in addition to it. A prerequisite to ensure that this happens would be the integration of complementary medicine within the official health care system.

Regarding the clinical effectiveness of Homeopathy, the Action concluded (1999): Recent comprehensive systematic reviews have shown that about 190 controlled clinical trials have been performed on homeopathic remedies. About 120 of these trials were randomized. The number of uncontrolled prospective clinical studies on homeopathic treatment strategies is relatively small apart from the area of complex remedies (combinations of several homeopathic). The two recent meta-analysis have shown that overall the available clinical trial evidence suggests that homeopathic remedies can have an effect over placebo. Due to the often insufficient quality of the trials and the lack of independent replications of defined study models this evidence is not (yet?) compelling. One set of trials provides some evidence that the use of one remedy (Galphimia) in low potencies has a reproducible effect over placebo in the treatment of pollinosis. The overall quality of the trials is acceptable; however, the analysis of the trials does not meet the stated standard (intent-to-treat-analysis), and despite being multicentre-trials, all were coordinated by the same principal investigator and therefore cannot be interpreted as independent replications. Another meta-analysis of three controlled trials has been published which claimed reproducible effects over placebo for the treatment of allergic conditions using isopathic nosodes. These studies were performed in different settings but again coordinated by the same principal investigator. Furthermore, the treated conditions were not identical (pollinosis and allergic asthma). In conclusion, for both analyses, confirmation by independent replications would be necessary before the evidence became compelling. Clinical research on homeopathy has been focussing almost completely on the question “is it placebo?” This general question ignores the fact that homeopathy is used in different ways (of which some, theoretically, might be effective and others not) and for a wide range of conditions. The reason for this generalised approach is the fact that homeopathy seems extremely implausible to academic medicine and the main motive for research so far has been to “justify” homeopathy to the scientific establishment. The resulting research is of questionable relevance for actual medical practice since the study models very rarely reflect actual practice. As is the case for acupuncture, we recommend that research on homeopathy should also include investigation of actual practice.

Safety

In 2008, a systematic study of the safety of homeopathy compared with conventional medicine, ref 29, concluded that overall patient satisfaction with homeopathic care was significantly higher than with conventional care, even taking into account the higher percentage of chronic and severe conditions in the homeopathic group. Given that conventional medicine regards all homeopathic therapy as placebo, direct risks resulting from homeopathic treatment seem unlikely, at least beyond a certain level of potency (homeopathic dilution). However, low potencies can contain physiologically significant concentrations of toxic substances (e.g., heavy metals). Homeopaths rarely discuss the possibility of side effects of homeopathy. So-called “first aggravations” - a worsening of symptoms soon after applying a treatment, generally thought to precede a significant improvement - are reported in case material quite frequently but not interpreted as side effects. It is unclear whether any risks are associated with such “first aggravations”. Indirect risks (harm resulting from a failure to apply an effective treatment) are considered more important in
homeopathy but little empirical data is available. For example, a case of malaria has been reported in a patient who tried to prevent malaria by homeopathy instead of standard drugs. In conclusion, based on existing knowledge, homeopathy seems to be a relatively safe therapy.

Regarding **fundamental or preclinical research** (Annexe IV - 162 papers, ref. 12 and 13-14), the fact that one third of publications have been published in international peer-reviewed journals gives confidence that these publications are of a high scientific quality. A literature classification using not only conventional quality criteria but also unconventional criteria (in respect of homoeopathy) showed that half of the papers considered were of the best possible quality. It is also interesting to note that of those papers published in international peer-reviewed journals, two thirds were considered to be of high value. Even good conventional methodology is not of itself adequate for research in Unconventional Medicine, and other approaches to the homoeopathic phenomenon are required. It was therefore possible to classify papers according to the conceptual models used. Most papers report positive results but unfortunately there is rarely any independent replication, even though the experimental models are usually internally reproducible and give consistent results. For each basic research model, every laboratory which tries to reproduce a result has to go through a learning and standardization process. The few published negative results are most commonly from a first testing of a new model or an early replication attempt in a new laboratory. Even though all these positive results constitute a very encouraging demonstration of the activity of homoeopathic potencies, there is still a need for more research, more external replication and more research on the similia principle. After this literature review, we can at least conclude that arguments against research on Homoeopathy are no longer supported. A sound scientific hypothesis can be formulated about working mechanisms of homoeopathic dilutions, and recent publications open the door to a better understanding of the effects of homeopathic medicines (see below).

1.4 Recent developments

Since the publication of the Action COST 4 report (1999), substantial progress has been made in clinical and fundamental research.

**Clinical research**

Large observational studies have demonstrated that homeopathy can improve quality of life in chronically ill patients. 


A review of clinical trials in homeopathy reported from 1975 to 2002 found 93 studies comparing homeopathy with placebo or other treatment. Positive effects of homeopathy were found in 50. The evidence favoured a positive treatment effect of homeopathy in: allergic rhinitis, childhood diarrhoea, fibromyalgia, influenza, pain, side effects of radio-/chemotherapy, sprains, and upper respiratory tract infection.


Swiss Health Technology Assessment (HTA) report 2011

An English translation of a Swiss HTA report on Homeopathy was published in the UK on 30th November 2011. The 2006 HTA report on homeopathy was commissioned by the Federal Social Insurance Office (FSIO) within the context of an overall evaluation of Complementary and Alternative Medicines (CAM). It was written by a team of German speaking academics and edited by G Bornhöft & F Matthiessen of Witten/Herdecke University in Germany. The HTA methodology addressed not only the question of effectiveness of a particular intervention but also the questions of effectiveness of a therapy in everyday use (i.e. real world effectiveness), how it was used, its safety and its cost-effectiveness. The report exhaustively reviewed the scientific literature in homeopathy, summarising 22 reviews, 20 of which show positive results for homeopathy. Four of these showed strong evidence that homeopathy, as a system of medicine, is efficacious. It also found strong supporting evidence for the homeopathic treatment of allergies and upper-respiratory tract infections. The comparative meta-analysis by Shang et al which appeared in the Lancet in 2005 and was heralded by the Lancet’s editor as “The end of homeopathy” was, according to Bornhöft & Matthiessen, commissioned by the FSIO as a part of this same assessment of CAMs. It was originally intended as an investigation of the quality of homeopathy trials compared to those of conventional medicine. In the HTA report, the authors analysed the Shang et al 2005 study, stating that, “Although we cannot conclude from the previous remarks [about the Shang et al 2005 study] the opposite conclusion - that homeopathy is effective - we can say with certainty that the Shang et al 2005 study does not prove that homeopathy has no effect.” The report also presented the results of the quality assessment of homeopathy trials, concluding that “studies of homeopathy and phytotherapy were of better quality than comparable conventional medicine studies”.

The Bornhöft & Matthiessen HTA report ends with this statement: “In conclusion we have established that there is sufficient supporting evidence for the pre-clinical (experimental) as well as clinical effects of homeopathy, and that in absolute terms, as well as when compared to conventional therapies, it offers a safe and cost-effective treatment.”

‘Homöopathie in der Krankenversorgung. Wirksamkeit, Nutzen, Sicherheit und Wirtschaftlichkeit.’

English Title ‘Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs.’
by Gudrun Bornhöft and Peter F. Matthiessen (Editors), 2011.

Fundamental research


1.5. Objectives of the homeopathic research community

It has now been demonstrated that by adapting trials to the complexities of the homeopathic system, effects can be detected which were considered non-existent by conventional scientists. Successful and extensive efforts have been made in clinical trials. Both conventional methodology and the selection of subjects for study have been adapted, in particular by selecting diseases and patients that are expected to respond to a specific remedy, thus allowing comparison with a placebo (see also ref 27). However, other studies, on quality of life for example, do not clearly show the impressive effects that users have always reported. All this calls for methodological studies, to discover how ambiguous results from conventional methods can be avoided by taking into account homeopathy's individual prescribing, its consideration of the whole human being, and the use of classification to provide clues in complex situations.

There is a need to communicate to other disciplines the benefits of such an approach and to explain better those features which have not yet been described clearly enough. Some disciplines currently use similar methodologies, whilst others reject them through a lack of understanding.

This could force a drastic change in medical evaluation, ref 21, where some urgent questions need easier answers than the rather unwieldy processes of genomic characterisation currently in development.

This means that studies of the actual activity of homeopaths are also needed, which justifies the data collection projects currently underway for the improvement of their own practice. There are certain limitations imposed by the requirements of confidentiality, because of the wide range of personal details shared by the patient in consultations. Moreover, medical intuition is also at work, which makes it difficult to record all the relevant information fully.

Beyond the aims of purely medical research, there is scientific curiosity to be satisfied – what exists in the remedies, where none of the initial active molecules should still be present? Current trends in chemical physics suggest that a promising perspective may derive from the influence of electromagnetic waves on the yields of chemical reactions; single molecule spectroscopy provides tools for observing the environment of active molecules in intermediate dilutions, and theoretical calculations give new results about the complexity of water as a solvent. Such exotic interdisciplinary studies need more respectability than they currently enjoy. A logical starting point would seem to be a physical description of dynamised solutions containing non-negligible concentrations of solutes.

1.6. Research infrastructure and methodology

When broadening the horizon of homeopathic research we have to acknowledge that different approaches require different research methodologies.

Reports from different countries and institutions (WHO 2002, ref. 18, WHCCAMP USA, 2002, ref. 19, House of Lords 2000, ref. 20, Jonas 2001, ref. 32) point out that the average quality of research in complementary and alternative medicine (CAM), including homeopathy, was poor.

The House of Lords Committee described a vicious circle: “Several reasons have been put forward to explain why so little high-quality CAM research is being done. The five most common reasons suggested to us are: a lack of research training across the CAM professions; a lack of research funding available for CAM projects; a poor, almost non-existent, research infrastructure within the CAM sector; a lack of interest in this field of research by conventional scientists who are trained in research methodology; and finally methodological issues, with many CAM practitioners believing that conventional research methods are not suitable tools with which to investigate CAM.”

To the priorities for research in homeopathy we must therefore add:

1. Developing proper methodologies for research in homeopathy.
2. Training researchers in homeopathy, research methodology and epidemiology.
3. Collaboration between centres of excellence in different countries in Europe in order to establish an infrastructure for research in homeopathy.
1.7 Homeopathic Pathogenetic Trials & Clinical Verification

Following Hering’s Guiding Symptoms, the clinical verification of homeopathic symptoms is one of several steps needed to characterise a symptom so that it can be used for homeopathic treatment:

**The possibility**: A substance provokes some symptoms; in some cases these might even be toxic.

**The probability**: When this substance, diluted and dynamised, has provoked various symptoms on volunteers in good health (first Homeopathic Pathogenetic Trial).

**The confirmation**: When this same substance, diluted and dynamised, given to volunteers in good health, has confirmed some of the symptoms observed in a previous pathogenesis and has provoked probable new symptoms (following Homeopathic Pathogenetic Trials).

**The corroboration**: An examination of the occurrence of the probable symptom and its correspondence to the known phenomena of physiology and pathology.

**The clinical verification**: In actual illness, the specificity of the probable symptom, confirmed and corroborated, is verified by obtaining clinical results.

Such research activities are of the greatest importance to prove and improve the success of homeopathy; they are part of the scientific evaluation of homeopathy because they comprise the foundations on which homeopathy has been built.

1.8. Aims and contents of this report

This report is intended to help homeopathic researchers develop a common strategy or structured framework, following a step-by-step procedure to evaluate homeopathy. This type of approach to research provides a structure or a strategic “backbone” connecting different fields of research, identifying successive steps which are required to further our understanding of various aspects of homeopathy. The advantage of such an approach is that knowledge gaps can be identified at an early stage and coherence between research groups or research activities is improved.

The aim of this ECH report is therefore to identify different research activities in clinical and fundamental research which will help researchers develop a systematic strategy to evaluate different aspects of homeopathy.

This report continues with a brief description of homeopathy as a method and its specific concepts of health and disease. This is necessary in order to understand its conceptual depth and therapeutic possibilities (chapter 2).

Next, the two main fields of research in homeopathy are described:

- Clinical research (on human beings and animals) is dealt with in chapter 3
- Fundamental research (in laboratories) is described in chapter 4.

Finally, several targets for homeopathic research are defined in chapter 5.
2. **HOMEOPATHY AS A METHOD**

2.1. **Basic principles**

Homeopathy is a system of medical practice based on three pillars:
- the similia principle
- the use of diluted and dynamised (or sucussed) medicines or remedies
- the homeopathic methodology.

**The similia principle**

This principle implies that substances / remedies that cause symptoms when applied to healthy biological systems can be used to treat the same symptoms in diseased biological systems. The similia principle, which forms the fundamental basis of homeopathy, is specific to homeopathy in the sense that it has not been recognised, accepted or studied by mainstream medicine.

**The use of diluted and dynamised (or sucussed) medicines**

Homeopathic medicines, some of which in their crude state are potentially toxic, are prepared according to a specific process of successive dilutions and succussions (for liquid preparations) or successive triturations (for solid preparations) – this process is called potentisation – in such a way as to nullify their toxic properties. A number of variations exist in both the dilution steps and the way in which succussion is performed.

**The homeopathic methodology: the individualisation**

The key to successful homeopathic treatment is identifying the similarity between the effects of the original substance in healthy people and the pattern of illness in the individual who is ill (Swayne, ref. 13). Homeopathic treatment is highly individualised – the patient’s personal physical and psychological characteristics, his/her clinical picture, diagnosis, aetiology, constitution, and any present, past and family illnesses are all relevant and significant.

Two centuries of homeopathic practice has not altered these three basic principles.

2.2. **Specific concept of health and disease**

The basis of homeopathic thought is that health is not a static condition but a dynamic process that tends to maintain a state of optimum equilibrium. This concept presupposes a built-in self-regulation mechanism, which protects against a loss of balance. Disease reflects an intensified attempt to restore an out-of-balance state, resulting from disturbing physical, chemical, biological and emotional factors.

Disease is conditioned by susceptibility and it manifests itself through symptoms in the mental/intellectual, emotional and physical planes. This self-regulation mechanism is regarded as responsible for protecting against a loss of balance as well as for its restoration. All that a doctor can do is to assist the process of restoration, to stimulate this self-regulation or self-recovery mechanism.

Homeopathic medicines are supposed to induce a process of reorganisation of vital functions by stimulating this self-regulation mechanism. This reorganisation can result in complete cure in cases where the symptoms derive only from functional derangement. The therapeutic possibilities, of course, depend on the extent to which the organism is able to recover. The more structural the changes that have been caused by the deregulation, the more partial a recovery will be. Limitations are specific surgical indications, deficiency diseases and very serious diseases in which gross anatomical changes have evolved. If a disease process has come to an end and the tissue damage has become irreversible, homeopathy may only have a palliative or relieving effect.

Homoeopathy is used to treat a wide range of disorders; in the Scientific Framework of Homeopathy
report (see www.lmhint.net) we found the following main areas had been scientifically investigated: trauma and pain, respiratory infections, mental and psychological disorders, pollinosis and rheumatology. Homeopathy can even offer therapeutic options where other treatments have failed or plateaued, where they do not exist for the problem, or where they are contraindicated or not tolerated.

2.3. **Homeopathic medicines**

Homeopathic medicines, mostly called remedies, are of botanical, chemical, mineral, zoological or microbiological origin. They are prepared from products, substances or compositions, called homeopathic stocks, in accordance with a homeopathic manufacturing procedure described by the pharmacopoeias currently used, officially, in the Member States. They are obtained from stocks by the process of potentisation, i.e. successive dilutions and succussions for liquid preparations and successive triturations for solid preparations.

2.4. **Homeopathy in clinical practice**

Homeopathic treatment is aimed at methodically improving the level of health of an organism by the administration of proven diluted and dynamised (or succussed) medicines, which are individually selected in accordance with the similia principle. The symptoms of a diseased organism, the “disease picture”, are classified and interrelated in such a way as to trace patterns that match with the “remedy picture”, i.e. the symptoms provoked by a remedy in a healthy organism. The more peculiar and individual the symptoms are, the more indicative for a certain remedy. If the similarity is great enough, the original disease or complaint does not recur after discontinuing the administration of the remedy. In case of incomplete similarity only partial or temporary effects are noticeable. Homeopathic treatment is compatible with other medication, but a homeopathic doctor seeks to reduce medication to a minimum.

Practical experience has shown that a hierarchy of functions plays a role in the application of the similia principle. Symptoms and signs that arise from higher functions (like emotional symptoms or individual patterns of responding to environmental factors) appear to be more indicative within the frame of reference of the similia principle. Even if the patient seeks help for somatic complaints (like headache or gastritis), all hierarchical levels of the patient –mental, emotional and physical– are methodically screened and the highest level of disturbance –from a hierarchical point of view– is discovered. Both human beings and animals may successfully respond to a homeopathic treatment. However, since mental, emotional and individual symptoms are more difficult to elicit in animals, in veterinary practice symptoms lower in hierarchy often lead to the most appropriate remedy.

3. **CLINICAL and SOCIO-ECONOMIC RESEARCH**

3. 1. **Introduction**

In general, “clinical research” is an umbrella term for a hierarchy of research methods ranging from uncontrolled clinical observations to controlled experimental studies (Figure 1). In order to assess the value and increase our knowledge of homeopathic therapy, European researchers of homeopathy wish to deploy the full range of these methods, including epidemiological studies and randomised clinical trials. This approach emphasises effectiveness research and efficacy research.

The following steps can be distinguished:

a) Data collection in homeopathic daily practice for quality assurance
b) Socio-economic studies to evaluate the spectrum of diagnoses, treatment and costs of therapy
c) Clinical studies to investigate effectiveness and efficacy

In addition, research on other aspects of homeopathy should be encouraged and supported.
d) Homeopathic Pathogenetic Trials – to describe and validate homeopathic remedy pictures.
e) Process analysis of information collected routinely to improve the quality of treatment, including safety, (quality assurance) and to increase our knowledge of symptom aggravation, syndrome shift, etc.

1-Effectiveness = the extent to which a specific intervention procedure, regimen, or service does what is intended to do for a specified population when deployed in the field under normal circumstances.
2-Efficacy = the extent to which a specific intervention, procedure, regimen, or service produces a beneficial result under controlled conditions.

3. 2. Effectiveness and efficacy research in homeopathy

Due to the relative lack of epidemiological information, most studies are undertaken without proper knowledge of basic information, such as the optimum length and frequency of treatment, the dynamics of disease manifestations in patients under treatment, or the success of treatment for specific types of disease. This emphasises the importance of data collection. On the basis of such information it would be possible to design prospective observational studies to obtain more systematic information about the effects of homeopathic treatment under normal clinical conditions. This could be done either with or without a comparison with conventional treatment. As a further step, it would be possible to select specific diseases for which efficacy and effectiveness studies (clinical trials) could then be conducted.

3. 3. Economic evaluation of homeopathy

Cost-effectiveness is an integral part of health care policy, and in some European countries is a prerequisite for the approval of new drugs and therapeutic methods. Because homeopathic drugs are generally inexpensive and homeopathic treatment strategies do not usually include the use of costly diagnostic procedures, it can be hypothesised that homeopathy may be effective in cutting health care costs. In order to test this hypothesis, it will be necessary to develop a programme for the health economic evaluation of homeopathic treatments. Due to differences in health care systems across Europe, we suggest conducting this research programme across a range of European countries. Some studies already carried out indicate cost-effectiveness (directly or indirectly) for homeopathy.
Figure 1: A Strategy for clinical and socio-economic research

- Socio-economic studies
- Clinical trials
- Prospective observational studies

- Information flow
- Feedback
- Process analysis
- Research area

- Data collection
- Outcome analysis

- Consultation

- Homeopathic knowledge base
3. **Homeopathic Pathogenetic Trials**

Homeopathic pathogenetic trials, or “provings”, are a type of research in which compounds are tested on healthy human volunteers in order to observe as many effects as possible, at a non-toxic level. This careful experimentation is a prerequisite for identifying the true pathogenetic picture of a homeopathic medicine, i.e. its capacity to alter the state of health. Such homeopathic pathogenetic trials can in fact be considered as a type of phase one study.

Testing of potential remedies on volunteers and describing the induced symptoms in order to establish the "remedy picture" has been performed since the very start of homeopathy. Hahnemann carried out the first systematic study of drug action in the history of medicine, and this method, so essential for evaluating the indications for homeopathic remedies, has continued ever since, although over time the procedures have changed. Current protocols for testing new substances (or retesting existing substances which have been incompletely tested) are in accordance with modern pharmaceutical and Good Medical Practice (GMP) procedures.

It is of the essence that homeopathic medicines are tested on human beings rather than animals. The reason for this is that disease has two distinct forms of expression, namely the subjective symptoms which include types of pains, emotions and other sensations in addition to the tissue changes or objective signs. In particular, the subjective symptoms are of paramount importance because they help to individualise a patient in their illness and thus to select a homeopathic remedy that matches this individualised state of illness.

A review of homeopathic pathogenetic trials has shown that nearly 150 such studies (ref. 22), of a wide range of substances, have been conducted in Europe since 1945. The methods used, however, have varied considerably and there is therefore a need for methodological development to refine and standardise the methodology of homeopathic pathogenetic trials. Establishing a standard for homeopathic pathogenetic trials has been a primary objective of the ECH.

Apart from improving the methodology of homeopathic pathogenetic trials, several additional activities should be promoted such as:

- establishing the priorities for retesting currently used remedies.

Some information in old standard homeopathic texts and databases is probably not completely reliable and needs to be verified.

- establishing the priorities for what kinds of new remedies are to be evaluated.

Testing the large number of plants, minerals and animal species existing in the world which have not yet been used as remedies could undoubtedly increase the therapeutic possibilities of homeopathy even further.

- extracting useful information from an evaluation of toxicological data (evidence-based clinical toxicology), of side-effects of remedies, etc.

In various studies, accidental exposures to toxic substances such as insecticides, heavy metals, etc. have been carefully recorded. This information can be of relevance either to validate or to extend remedy pictures of compounds used within homeopathy.

- developing a policy on the kinds of symptoms which should be inventoried or studied in homeopathic pathogenetic trials (biochemical changes in the body, physiological and emotional alterations, types of dreams, etc), as well as establishing their relevance in relation to self-recovery processes.

- establishing the hierarchical order of symptoms. In this respect it is of importance to differentiate between the quantitative and qualitative characters of symptoms.

A symptom which is induced by a substance in a majority of healthy volunteers may offer less information than a specific symptom which is induced in a minority of individuals but which may refer to the essence of the tested substance. This is the corroboration of a symptom.

- clinical verification of these symptoms in actual, ill patients is the last but absolutely essential step of this type of research. The correspondence of the probable symptom, confirmed and corroborated, is verified by the obtained clinical results.
establishing a database and a network for exchange and evaluation of data from observational studies, etc.

3.5. **Homeopathy in the livestock farming sector**

In the livestock farming sector, homeopathic medicines may replace antibiotics, hormones and other drugs for certain cases of infection, inflammatory diseases or reproductive disorders, or may shorten the duration of antibiotic treatment. Homeopathic dilutions from $10^{-6}$ M onwards will create either no or negligible residues, and these can be shown to be in the low ppb range for even worst case scenarios. In view of rules which are soon to be introduced regarding organic livestock farming, the development and introduction where possible of homeopathy into the livestock farming sector is particularly important. This has the potential both to protect consumers better from pharmacological residues in animal products and to improve conditions for livestock. Research in this field is necessary and ongoing (ref. 23).

3.6. **Auxiliary studies**

This research field relates to items or phenomena on which homeopathic treatment is based or which are frequently observed within homeopathic practice, such as “self-recovery”, “placebo effect”, “semantics”, “symptom aggravation”, “adverse effects” and “syndrome shift”. Research in all of these fields may eventually be required to improve our understanding of all aspects of homeopathy, as well as its relation to mainstream biomedical knowledge. It should be noted that these phenomena are probably not exclusive to homeopathy, but may also be observed in mainstream medicine as well as in other forms of complementary medicine. (ref. 24-29-30)

4. **FUNDAMENTAL RESEARCH**
4.1. Introduction

Constraints to the acceptance of homeopathy which are most often cited by opponents are the lack of a scientific basis and the absence of a theoretical model for homeopathy. Fundamental research is a prerequisite to improving our knowledge of the basis of homeopathy (the similia principle and specific preparation of remedies) and to increase our understanding of the working mechanism of its remedies.

The HMRG (ref. 7) recommends the replication of models in which an effect of high potencies has previously been claimed. Although it is recognized that for such validation it is important for different workers to repeat successful claims in simple model systems in well controlled, multi-centre trials, the ECH favours an increase and extension of fundamental studies. This field of research should aim to open the ‘black box’ of homeopathy.

Within the existing fundamental studies of homeopathy (ref. 12-13-14), the majority (>90%) of such research is concentrated on demonstrating an effect of diluted and dynamised (or sucussed) agents or remedies. Hardly any research is directed towards the similia principle; neither are activities organised in a structured way to elucidate the underlying mechanism of high potencies, or to discover ways to optimise their effect. From a strategic point of view, this imbalance between research aimed simply at demonstrating effects and explanatory research is far from satisfactory, especially when such effects cannot be explained.

Fundamental research into homeopathy can be divided into two main fields:
- the similia principle
- the preparation, mechanism of action and effect of diluted and dynamised (or sucussed) remedies.

4.2. The similia principle

Curative approach:
The similia principle states that remedies or conditions that cause symptoms in healthy biological systems can be used to treat the same symptoms in diseased systems. This curative approach can be used in any biological system (cell, organ, plant, animal, human being) which is in a diseased or disordered state. The stimulation of recovery by any compound applied according to the similia principle can then be studied. The essential question is how far the extent of stimulation of self-recovery by low doses is related to the degree of similarity. For research purposes, the similia principle can be divided into two principal modes, homologous and heterologous. In the homologous mode (also called isopathy), the same compound is used to perturb the biological system and subsequently, in a lower dose, to cure it. In the heterologous mode, different substances or drugs (which may or may not have analogous effects) are used to perturb and subsequently cure.

No single type of experiment is on its own sufficient to investigate the similia principle, since multiple aspects must be analysed and demonstrated, either in parallel or sequentially. A research programme is therefore required using biological models which allow a systematic unravelling of the various aspects. A full analysis of the similia principle requires a number of steps, described below at the cellular level, but these can also be applied to more complex systems such as organs or whole organisms (plants and animals).

Step 1. Selection of parameters for self-defence and self-recovery which will be evaluated. The effects of various compounds or toxins on normal undamaged cells is studied; this is analogous to the description of the symptoms induced by substances at higher system levels known within homeopathy as "provings", "remedy pictures" or "homeopathic pathogenetic trials".

Step 2. The homologous mode of the similia principle. Can the self-defence and self-recovery, induced by disturbing a cell culture with a sub-lethal toxic agent, be further stimulated with a low dose of the identical damaging substance?
Step 3. The heterologous mode of the similia principle (specificity of low dose stimulation)
Such studies of specificity require results from steps 1 and 2 which will include:
- “Homeopathic Pathogenetic Trials” of different compounds at the system level under study.
- Development of methods to determine the degree of similarity or otherwise between the symptom pattern of the disordered/diseased system and the remedy picture of the proved compounds. The likelihood that a given compound will stimulate self-recovery may then be predicted from the degree of similarity.
- Measurement of stimulation of self-recovery by low doses of heterologous compounds (ranging from more to less similar). This step allows the above-mentioned prediction to be verified and shows whether the magnitude of stimulation correlates with the degree of similarity.

Preventive (i.e. protective or prophylactic) approach.
Although the similia principle is mainly applied for therapeutic (curative) purposes, it is also used in a prophylactic (preventive) context. Essentially, the same steps are taken as for the curative approach:
1) Definition of the parameters of tolerance,
2) Stimulation of tolerance/desensitization to a high dose of something by a previous incubation with a low dose of the same substance,
3) Establish the specificity of the stimulation of tolerance by low doses of analogous compounds.
In this field of research the relation to ‘hormesis’ and ‘the adaptive response’ should be further established, especially in respect of specificity.

Potencies vs. dilutions in the study of the similia principle
In essence, the similia principle can be studied without the use of potencies (the founder of homeopathy, Hahnemann, introduced potencies ten years after he first described the similia principle). The research strategy described above to verify the similia principle can therefore be carried out using both normal dilutions as well as low or high potency preparations, preferably in a range of potencies.

4.3. Preparation, mechanism of action and effect of diluted and dynamised (or sucussed) substances in various biological systems

4.3.1. Preparation of diluted and dynamised (or sucussed) substances
An important aspect of homeopathy is the specific way in which remedies are prepared, i.e. diluted and dynamised (or sucussed). There are a number of different protocols for potentisation, but there is as yet insufficient consensus regarding the type of potency to be used in different conditions, how to store potencies, which chemical, physical or informational model is most appropriate to explain their mechanism of action, etc. Needless to say, increasing our knowledge of these aspects is crucial to improving the quality and the stability of the potencies used.

4.3.2. Mechanism of action of diluted and dynamised (or sucussed) substances
It is suggested that potentisation changes the characteristics of the substance in such a way that the information content of the remedy is of increasing relevance, especially at high potencies. For research purposes, a rough division can be made into low and high potencies depending on the way in which an effect might be explained.
- Low potencies, i.e. substances which have been diluted and dynamised (or succussed) only a small number of times (for example D12 or C6 and below). Since these remedies contain a relatively large concentration of molecules of the original substance in the milli- to picomolar range, effects of low potencies may possibly be explained in terms of conventional biochemistry and biomedical terminology.
- High potencies, i.e. substances which have been diluted and succussed beyond Avogadro’s number (for instance D24 or C12 and above), are unlikely to contain any molecules of the original substance. An explanation of any observed action of high potencies appears to require knowledge of other fields, such as physics and information theory.

There will be a transitional range (between D12/C6 and D24/C12) where the informational aspect becomes more important than the molecular aspect.

The claims made for very high, so-called ultra-molecular dilutions, (i.e. dilutions which, according to Avogadro’s Law, are very unlikely to contain even a single molecule of the starting substance) and which are commonly used in homoeopathy, are very challenging and raise fundamental scientific questions. Until quite recently it was possible to argue that these extreme dilutions had no real effects, and that all the apparent clinical effects of homoeopathy were due to placebo or non-specific effects. However, the growing evidence of their effects from rigorous, randomised controlled trials is making such a position increasingly untenable.

A possible explanatory hypothesis for the mode of action of extremely high dilutions is the Information Medicine Hypothesis, which proposes that the actions of homoeopathic medicines should be understood in terms of physically stored information rather than in chemical terms. The Information Medicine Hypothesis states: "Under certain circumstances, water (and perhaps other polar solvents) are capable of receiving and storing information about substances with which they have previously been in contact and of transmitting this information to pre-sensitised bio systems". If verified, this hypothesis would represent an important scientific advance, with implications extending far beyond homoeopathy.

4.3.3. Effect of diluted and dynamised (or sucessed) substances

To examine the claims that remedies which have been prepared in a specific way do in fact show specific characteristics, will require models and data from the fields of both chemistry and physics. This field of research is mainly concerned with the demonstration of an informational content of high potencies by the evaluation of both biological effects and structural aspects of these potencies.

\[
\begin{array}{c}
\text{evaluation of potentisation and of best possible manufacturing conditions} \\
\downarrow \\
\text{potentisation} \\
\text{material} \\
\downarrow \\
\text{information} \\
\downarrow \\
\text{effect} \\
\end{array}
\]

: biological organisms (cell, plant, animal, human)
: physical methods

a. Informational aspects of high potencies as measured in biological systems

This research is aimed at determining any effect in any biological organism (ranging from bacteria to man) from the application of high potencies.

b. Informational or structural aspects of high potencies as measured by physical methods

This research aims to demonstrate a change in the structure of the solvent in diluted and dynamised (or succussed) remedies. Alterations in the structure of water, the presence of an electromagnetic field and the oscillations of this are current topics for speculation; physical methods which are able to analyse these aspects should be used or developed to further our knowledge in this field of research.

Priorities in systematic research on high potencies:
- In the first instance, research should be focussed on validating models which are able to demonstrate an informational content of the potency, using biological and/or physical
methods. It is important to be able to reproduce any results in independent laboratories. A variety of model systems could be selected for these studies.

Secondly, once a model has been clearly defined in which an effect can be repeatedly demonstrated, the following questions can be addressed:

• Do different steps in preparation (materials, the type of potentiation procedure, etc.) give rise to variability in effect?
• Is the stability of the potency influenced by electro-magnetic fields, temperature, duration of storage, etc.?
• Can the information in the potency be copied?
• What is it in the cell or organism which functions to receive the information contained in the potency?
• How can the storage and transmission of information be explained?

4.4. Auxiliary studies

This research field relates to an explanation of phenomena which are observed in homeopathic practice, such as “self-recovery”, “placebo effect”, “symptom aggravation”, “adverse effect” and “syndrome shift”. In addition, it also relates to fundamental issues such as “hormesis”, which is the paradoxical phenomenon that a toxic substance produces stimulation at a lower concentration. This non-specific stimulation of many physiological processes, including growth and longevity, by low doses of many kinds of toxic compounds or stressful conditions, has attracted the attention of homeopathic practitioners as a possible explanatory model for homeopathy. Finally, in order to explain the high potency effect, physical phenomena such as turbulence, chaotic processes in the preparation of homeopathic remedies, the structure and “memory” of water, and various electromagnetic phenomena may need to be invoked.

In the long run, all of these research fields may need to be addressed before we can complete our understanding of every aspect of homeopathy, including its relation to mainstream biomedical knowledge. A full explanation of these phenomena may require an approach based in systems theory, as well as specific methodologies for studying complex biological systems.

5. TARGETS AND PRIORITIES

Homeopathy cannot be demonstrated in any single type of experiment – multiple aspects have to be analysed and demonstrated, either in parallel or sequentially. The ECH therefore stresses the need to
develop research programmes that allow the systematic unravelling of the many aspects of both clinical and fundamental research.

**Clinical and Socio-Economic research**

Various fields of research are relevant, ranging from effectiveness and efficacy research, cost-effectiveness and safety studies, to homeopathic pathogenetic trials.

Effectiveness and efficacy research requires a number of sequential steps. Effectiveness research should range from simple data collection in daily practice, through observational studies, to outcome and cost-effectiveness studies based upon strict protocols. Efficacy research focuses on specific questions using randomised controlled designs.

The ECH considers the following steps to be essential:

1. surveys in daily practice
2. post-marketing surveillance
3. observational studies
4. randomised unblinded comparison studies
5. randomised clinical trials, including both the development of new trials and the replication of previous successful trials.

- Research on a range of aspects of clinical homeopathic practice should be stimulated, such as the steps in the diagnostic process, the various steps leading to the selection of a remedy and the development of treatment protocols in specific diseases.

- From a socio-economic perspective, the following studies are necessary:
  - demographic studies (who goes to see a homeopathic doctor and why)
  - satisfaction and quality of life studies
  - economic evaluation of homeopathic health care (cost-effectiveness)

- Homeopathic pathogenetic trials (provings) are necessary not only to improve existing knowledge of homeopathic remedies and the quality of homeopathic treatment, but also to extend the range of remedies used.
  - certain standards for this kind of trial have already been developed
  - many compounds need testing and retesting
  - toxicology studies are to be carried out and a database is to be developed

- Where possible, the development and introduction of homeopathy into the livestock farming sector is particularly important. This has the potential both to protect consumers better from pharmacological residues in animal products and to improve conditions for livestock.

- Various phenomena described within homeopathy need further research, such as initial aggravation, syndrome shift, disease substitution, and placebo effects.

- Revision of the homeopathic bibliography of homeopathic medicines and databases.
Fundamental and preclinical research

To improve our understanding of the scientific basis of homeopathy, a number of activities are required:

- A shift in emphasis is needed from fundamental research activities towards a more balanced distribution of research between the two fundamental aspects of homeopathy, i.e. the simila principle and the use of diluted and dynamised (or sucussed) remedies.

- A theoretical model for homeopathy is required which can express the processes underlying recovery from an application of the similia principle in terms of mainstream biomedical knowledge.

- The relation between the similia principle and hormesis, the paradoxical stimulatory effect of low doses of toxic substances, should be further analysed.

- A limited number of promising model systems, in which an effect of high potencies has been apparently demonstrated, should be replicated. Two or three test systems which are conceptually sound should be selected and developed further.

- The conditions in biological model systems under which optimum effects of (high) potencies occur should be further analysed.

- The relevance of physical phenomena such as turbulence and chaotic processes in the preparation of homeopathic remedies should be further analysed. It should also be determined whether the structure and “memory” of water and/or electromagnetic fields are of any relevance in the establishment of any effect of (high) potencies.
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