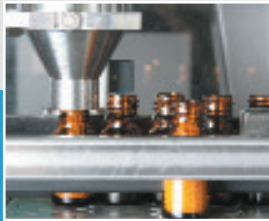


THE SCIENCE BASE OF HOMEOPATHIC AND ANTHROPOSOPHIC MEDICINE



*Over 200 years
of safe and effective use*

*"Homeopathy is a system of medical practice
aiming at methodologically improving the level
of health of an organism by the administration
of potentised medicines, which are selected in
accordance with the Law of Similars"*

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INTRODUCTION

Dear reader,

Since homeopathy was initiated and developed by Samuel Hahnemann about 200 years ago, there has been extensive documentation of clinical experience with this form of therapy. However, more scientific publications including randomised clinical trials (RCT) according to internationally accepted standards have only a relative short history. Systematic reviews of such trials only began around 1990 when, amongst others, Kleijnen (1991), Linde (1997), and later Jonas (2003) were able to show sufficient evidence to support effectiveness of homeopathic therapy.

An important point of consideration in homeopathic research is the need to increase the quality of the documentation. This requires substantial funding which is generally only available in exceptional cases, as manufacturers of homeopathic medicinal products are seldom strong enough to invest substantially in research, since patent protection is not available for medications which have been known for decades. Furthermore, the European Union and National Government Institutions very rarely provide funding for homeopathic research. This is surprising, considering the benefit of the low-cost of homeotherapy and the fact that it is a basically safe medicinal alternative to chemical drugs. The high degree of popularity in patients and health care providers would warrant a stronger engagement on their part.

The NIH (National Institutes of Health) in the United States is an encouraging example of how health politics can deal with clear evidence of positive effects of Complementary Alternative Medicine (CAM) - including homeopathy - on public health.

The Traditional Medicine (TM) section of the WHO is also engaged in guiding their member nations into a quality and safety-oriented understanding and employment of CAM therapies, including homeopathy. A specific review of the evidence base for homeopathy is intended for publication before the end of 2005, supported by the Region of Lombardy and the University of Milan. These are important examples of the increasing significance of homeopathy in public health.

The regulatory environment for homeopathic and anthroposophic medicinal products within the European Union is improving slightly. A first attempt to start a common market for homeopathic products was intended by the end of 2005, when mutual recognition of homeopathic medicines will be possible. This is only a modest, bureaucratic and incomplete start, enabling Europeans to receive free access to only a group of homeopathic medicines. Many products which have a therapeutic claim on their label remain excluded from that procedure. These will be available under national rulings of a few EU Member States only, basically only

where they have traditionally been used. Under the present European legislation they will still be excluded from EU-wide mutual recognition.

As yet, no acceptable proof of the working mechanism exists. There are some promising hypotheses, but the lack of a valid explanation, as to why dilutions beyond the presence of a molecule can have a therapeutic effect, still breeds scepticism.

Despite all the evidence, scepticism not only blocks progress in science but also in health politics. Conservative policy makers follow the sceptics rather than listen to the voice of the millions of citizens who are being deprived of safe and effective homeopathic medicines.

The aim of this brochure is to help interested politicians, NGOs and also journalists to obtain a better picture of the value of research in homeopathy - for the sake of public health, for an improved disposition towards funding of research in this promising field of health care and for the recognition of the needs of all those practitioners and consumer/patients looking for a legitimate alternative.

Max Daege

*President of the European Coalition on Homeopathic
and Anthroposophic Medicinal Products,*

Brussels, September 2005

CONTENTS

I. RECOVERY AT YOUR OWN PACE 8

Homeopathy stimulates the body's natural forces of recovery. It has limited side effects and does more than simply treat symptoms. In the European Union 130,000 doctors work with homeopathy. Member States have millions of users, however the social status of homeopathy varies from country to country. The European Commission favours further harmonisation of legislation.

II. BECAUSE IT'S SAFE AND EFFECTIVE 12

Over one hundred million Europeans use homeopathy. It is safer, cheaper and in many cases more effective than conventional medicine. The Council of Europe, the European Parliament and the World Health Organisation all plead for homeopathy to be integrated into the existing health care system and for more scientific research. One wonders why so little has happened in this respect.

III. SCORING ACCORDING TO THE GOLD STANDARD 16

It's a false premise to say that homeopathy lacks a scientific basis. Three out of four methods of research are well suited to homeopathic medicines. The "gold standard" for clinical research is the Randomised Clinical Trial. Homeopathy scores remarkably well if this method is employed correctly. Meta-analyses have also delivered favourable results which have been published in peer-reviewed magazines.

IV. EVERYTHING BUT PLACEBO 22

Homeopathy is sometimes referred to by sceptics as "placebo-medicine". But the study results indicate otherwise. Three extensive meta-analyses executed at academic level delivered positive outcomes. Today homeopathy, strongly based on decades of medical experience, has also become a modern and evidence based form of medicine.

V. NOT JUST A DILUTION

26

Can a sip of water without even one molecule of another substance heal a sick person? The discussion surrounding homeopathy often concentrates on high dilutions, ignoring the importance of potentisation, one of the fundamental rules of homeopathy. Homeopathic medicines are not just diluted, they are also succussed, and it is the joint action which determines their potency. It would seem that water has the capacity to take on the information of the substance during the process of potentisation and retain this memory even if there is no material substance present.

VI. ANIMALS HAVE NOTHING BETWEEN THE EARS 30

When a horse recovers from taking homeopathic medication, the success cannot be attributed to imagination or placebo effect. In researching homeopathic medicines on animals (and small children), complicated randomised, double blind studies do not seem appropriate. An animal does not speculate about its treatment. Hence, if a medicine works in veterinary use, it is effective.

VII. EXPERIENCE BASED KNOWLEDGE, THE ANTHROPOSOPHIC APPROACH 34

Anthroposophic medicine shares the holistic approach with homeopathy and offers something over and above regular allopathic treatment. Medical care and medicines are attuned to the individual. Empirical science plays a key role. Because of that, scientific research according to common comparative standards becomes complicated. A new study design is being developed, allowing for the empirical component as well as the patient individuality.

CONCLUSION

40

I. RECOVERY AT YOUR OWN PACE



Homeopathy stimulates the body's natural forces of recovery. It has limited side effects and does more than simply treat symptoms. In the European Union 130,000 doctors work with homeopathy. Member States have millions of users, however the social status of homeopathy varies from country to country. The European Commission favours further harmonisation of legislation.

"The European Parliament has taken the position that homeopathy – as well as other branches of non-conventional medicine – should be recognized. The Council of Europe welcomed the European Parliament's resolution on the status of non-conventional medicine."

(Dr. Ton Nicolai, MD, President of the European Committee for Homeopathy)

What is homeopathy?

Three out of four Europeans are familiar with homeopathy. One in four uses this form of therapy. There are 30,000 specialised medical doctors and some 100,000 general practitioners who offer their patients treatment with homeopathic medications (homeotherapy). Homeopathy is a popular, appreciated and in particular a safe kind of therapy. Its status varies strongly from country to country. In Germany and Austria homeopathic doctors are officially recognised. In Sweden and Slovenia they might face juridical persecution. Other countries have a mixture of recognition and prohibition on various aspects of homeopathic treatment

This ambivalent status is a direct consequence of the unique character of homeopathy. Modern western, science based medicine has a strong allopathic character. This means: an illness is dealt with by a therapy neutralising undesired symptoms. However, almost every medicine has its side effects which can be not only disturbing but also dangerous or even lethal.

Homeotherapy sets out from the opposite principle: it uses micro-doses of specific substances to provoke defence and self-regulatory responses rather than the conventional approach of blocking physiological reactions. The guiding principle is the Law of Similars¹ or the simile principle.

¹ "*Similia Similibus Curentur*" (like cures like)

The principle of homeopathy, the rule of similars, was practised more than 2500 years ago. Hippocrates, the Greek, considered to be the founder of western medicine, described the allopathic as well as the homeopathic model as serious forms of therapy.

The German physician Samuel Hahnemann, a pioneer in modern and systematic pharmaceutical research, is generally considered the father of modern homeopathy. Two hundred years ago he reformulated and elaborated its therapeutic principles.

It is an ancient idea but it fits the recent physical developments quite well. The simile principle is not the real reason why quite a few scientists – and in their wake also politicians and journalists – have difficulty with the concept of homeopathy. The real difficulty arises on the subject of dilutions.

In "classical" homeopathy practitioners work with extreme dilutions of the starting material; where in some cases they exceed Avogadro's number. That means that no molecule of the initial substance is present in the dilution anymore. Yet therapeutic effects are claimed from these medicinal products.

Sections 3, 4 and 5 will explain that these effects have been ascertained on the basis of both empirical and scientific clinical research. Beside that, fundamental

research has been performed in support of the various hypotheses of homeopathy's working principle.

The World Health Organisation is a proponent of traditional medicine, provided it has been proven to be safe and effective. After earlier reports of recommendation concerning traditional medicine in a broader scope and acupuncture in particular, they are now working on a report about the scientific status of homeopathy. More about this in chapters 3, 4 and 5.

The position of anthroposophic medicine is another story (see chapter 7). Its philosophy and history are different but the medicinal products have a resemblance with modern homeotherapy. This also applies to their status. According to the definition contained in the European Directive 2001/83/EC, homeopathic and anthroposophic medicines are medicinal products according to the law and therefore subject and entitled to all obligations and rights attached.

II. BECAUSE IT'S SAFE AND EFFECTIVE



Over one hundred million Europeans use homeopathy. It is safer, cheaper and in many cases more effective than conventional medicine. The Council of Europe, the European Parliament and the World Health Organisation all plead for homeopathy to be integrated into the existing health care system and for more scientific research. One wonders why so little has happened in this respect.

"These kind of products might work very well, whether alongside regular treatment or not"

(Dr. E. Borst, 1999, former Minister of Health of The Netherlands)

Homeopathy in our society

In the United States, statistics show that every year some 100,000 people die from the use of medicines; either because of side effects or as a result of a wrong prescription. In other words: for Americans, medicine-use ranks on the fourth place of the main causes of death. European data are hard to compare, but we know that in a country like The Netherlands, with an average health care system, 44% of patients receive the wrong medicines once in a while. The number of medicine deaths is estimated at "some hundreds" per annum, presumably more than the death toll of traffic. According to a Norwegian study, 18% of elderly hospital patients die from the side effects of medicinal products.

During the past decennia European citizens have become more conscious of the risks which accompany the use of medicines – in particular when used over a longer period of time. Simultaneously, there is an increase in the number of patients with chronic disease and it is here that the pharmaceutical industry has relatively little to offer. These two trends have strongly stimulated the demand for homeopathy. Its safety is well recognised – even with sceptics – and the best results have been achieved with chronic indications.

Various studies demonstrate that homeopathy users are more satisfied with their treatment and its effects than they are with a (previous) regular therapy. A clear example is the study performed in 2001 on the request of the Belgian association of homeopathic doctors.

Some 800 patients were treated homeopathically for various and quite serious complaints for which they had already received regular treatment for a longer period of time. Not less than 95% were (very) satisfied with the effect versus 20% who were happy with the former regular treatment. 89% stated that their health had improved versus 13% saying so about the regular treatment.

Well-being is a subjective perception. However, objective effects run in parallel to it. The number of visits paid to regular medical specialists decreased considerably after homeopathic treatment. More than half of the treated patients were able to reduce their medicine use significantly. This effect is not only a gain in health, it also represents an economic benefit. If these cost saving effects are extrapolated to all patients, this would have saved the Belgian state €775 million per annum.

Homeopathy belongs to the four most requested treatments within CAM (Complementary and Alternative Medicine). More than one hundred million European citizens use it. Insurance companies are familiar with the favourable effects of the best known CAM techniques.

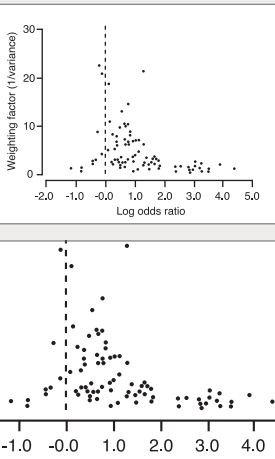
In all European countries, except Iceland and Ukraine, the costs are reimbursed via private health insurance or even the social security system.

The European citizen does not stand alone in his interest and demand for homeotherapy. Since 2003 the WHO has supported its member states in the integration of CAM into their national health systems. Six years before, the European Parliament expressed itself in favour of the recognition of non-conventional medicine and for research into safety, effectiveness and the possibilities of application. A year before the Council of Europe did the same. For the time being, in Europe, only the United Kingdom has given a financial impulse of two million Euros for scientific research in this area.

Moreover, the UK is the only Member State with five public homeopathic hospitals. Other countries like Austria, Germany, Italy, Spain and France have possibilities for homeopathic polyclinic treatment.

France is frontrunner with homeopathic education or teaching at eight universities, Poland with seven, Germany with five and Spain with four.

III. SCORING ACCORDING TO THE GOLD STANDARD



It's a false premise to say that homeopathy lacks a scientific basis. Three out of four methods of research are well suited to homeopathic medicines. The "gold standard" for clinical research is the Randomised Clinical Trial. Homeopathy scores remarkably well if this method is employed correctly. Meta-analyses have also delivered favourable results which have been published in peer-reviewed magazines.

"After three positive studies which all significantly demonstrate that homeopathy is doing more than placebo, I must assume that a high potency really works or assume that the Randomized Clinical Trial is a useless instrument"

(Dr. David Reilly – Glasgow, British researcher)

Science and homeopathy

"For the scientific acceptance of homeopathy, harder evidence is demanded than usual", says Dr. Fred Wiegant. The Dutch researcher was involved in two of the most remarkable research projects concerning homeopathy. Like his British colleague Vickers he concludes that scientific evidence for the effectiveness of homeopathy is systematically denied, "because the outcome doesn't please the sceptics". Even when the study is executed according to the strictest scientific standards, a result in favour of homeopathy is not readily accepted by a sceptic, "because homeopathy simply cannot be true".

Without the multiple, sometimes very high dilutions and the potentising process (shaking or succussion during manufacturing) homeopathy would have been accepted long ago. There is so much unequivocal clinical proof that any other medical therapy would likely have acquired recognition. In a number of European countries even acupuncture and phytotherapy are well accepted, although the working mechanisms of these treatments are not always clear either.

Over the past ten years significantly more clinical and basic research in homeopathy has been performed than in previous years, especially because the United Kingdom and the United States have provided considerable funding for research. Contrary to before, academic centres and regular peer reviewed magazines are no longer rejecting this subject outright.

One can distinguish four forms of research in which science checks a treatment or a medicinal product. Most frequently applied is the Randomised Clinical Trial; one group of patients receives a certain treatment whereas a control group receives a placebo treatment or a comparator product. Strict rules according to international standards are applied so that a patient is not aware of what is actually administered. In the strictest set up even the prescribers and the researchers do not know who received what. Only after the trial the code is broken and the outcome made known. This kind of research is also applied to research the effect of homeopathic medicinal products.

Epidemiological research - aims to determine the frequency of diseases and the reasons behind that frequency - encompasses extensive groups and a great number of years. These methods obtain an insight into the health effect of a certain life style or of long-term use e.g. of complementary and alternative

medicine. This type of research - setting out from the large numbers - suits homeopathy in a lesser degree since homeopathy is more individual and patient-oriented. Observational and outcomes studies study the effectiveness of a therapy under practical circumstances. The outcome is relevant for practitioners and patient. When a comparative set up is made, meaningful information can be obtained for providers and insurers.

Fundamental research sets out to satisfy a basic curiosity. What happens when A is added to B? Why is C slow and D quick? Much of this research is done in a laboratory setting. The unexplained working mechanism of homeopathy has been the objective of various fundamental research studies and their derivatives. Extraordinary discoveries have been made here. See chapters 4 and 5 for further details.

Researching the research could be the scope of the fourth form: the meta-analysis. This is a sort of super-screening which can be very enlightening. A meta-analysis is a statistical practice of combining the results of a number of studies. Analyzing the results from a group of studies can produce more accurate estimation of effects. However, and as known when looking at statistics, there is also the risk of misinterpretation.

The scores of research projects into (aspects of) homeopathy have been the subject of three meta-analyses during the past fifteen years, each time again with an unexpectedly favourable outcome for homeopathy.

Nevertheless homeopathy struggles to hold its own in a world geared towards researching conventional medicine.

As Ton Nicolai, President of the European Committee for Homeopathy (ECH), writes: 'Mainstream research studies most often ignore the basic rules of homeopathy and are usually without any value to actual homeopathic practice. In other words, the external validity is low and therefore there is a high risk of false-negative results. Especially the 'gold standard' randomised controlled studies (RCT) forces homeopathy into a straightjacket. The historical evidence, the case reports and 200 years practice on millions of patients: this 'soft' evidence can and should not be ignored'.

The French researcher Prof. Bastide is also openly questioning whether the Randomised Clinical Trial is really such an ideal instrument. This also comes from the homeopathy-critic Vandenbroucke, the Leiden professor in epidemiology. From the homeopathic and anthroposophic point of view a plea for different methods of research has already been made for longer than that (see also chapter 7).

A medical treatment can also be looked at from another angle, rather than at the effect of the working mechanism. Policy makers, like insurance companies, attach greater importance to cost effectiveness (health economics). In such case questions are asked like: "How satisfied is the patient with this kind of treatment?", "Can the patient continue his daily and professional duties during treatment?" or "Do we save cost with this approach?" Homeopathy scores well in these kind of studies. The users are very satisfied, their treatment is relatively cost effective and it often helps by reducing expensive allopathic care.

IV. EVERYTHING BUT PLACEBO



Homeopathy is sometimes referred to by sceptics as "placebo-medicine". But the study results indicate otherwise. Three extensive meta-analyses executed at academic level delivered positive outcomes. Today homeopathy, strongly based on decades of medical experience, has also become a modern and evidence based form of medicine.

"It is impossible to convince a person who thinks from one paradigm of the validity of another. However strong the evidence, a counter-argument can always be found"

(Science Philosopher Thomas Kuhn in "The Structure of Scientific Revolutions")

Striking outcome of research

"Really outstanding research, but I have to reject the outcome: homeopathy is not possible!" This is how a professor of epidemiology reacted on the outcome of the meta-analysis performed by the German researcher Linde. That analysis documented that the positive effect of homeopathy is almost 2,5 times the effect of placebo.

"Placebo effect²" always used to be the explanation by sceptics when a thorough piece of research demonstrated a positive effect of homeopathy. However, the three meta-analyses show that such an "explanation" cannot be maintained. Linde came to that conclusion at the end of his scientific report (1997).

A year before, a similar result was produced by a meta-analysis by the European Commission. One of the conclusions was that the chance that the measured homeopathic effect is based on a placebo-effect is 0.000036. Nor did the first and perhaps the most impressive meta-analysis by the Dutch Kleijnen research group leave any room for a different conclusion. The leader of the project was so surprised that he was prepared to honour the favourable result, even though the working mechanism was personally unacceptable to him.

² An effect created by (self) suggestion

The three meta-analyses have demonstrated important aspects. First of all that homeopathy - despite its non-conventional character - can also be researched with the usual scientific methods. In the second place that a considerable amount of research of good quality has been done. And finally that the overall conclusion from all good studies is: homeopathy has an effect which cannot be explained by placebo.

In a preliminary report, the World Health Organisation has collected a great number of studies published in peer reviewed magazines over the past twenty years including those with less favourable results.

There are a great many striking examples of thorough research, published in reputed regular professional journals presenting positive results for homeopathy.

Just to mention a few:

In 1986 Reilly administered patients suffering from hay fever highly diluted pollen. The result in the verum group³ exceeded the placebo group⁴ by seven times. Fisher selected fibromyalgia patients in relation to the homeopathic drug picture *Rhus toxicodendron* 6C through a regular diagnosis. In the verum group 25% fully recovered. Jacobs administered Nicaraguan children with acute diarrhoea individually attuned homeopathic medicinal products in high dilution. They recovered in three days compared to four days in the control group.

³ *The group of patients receiving the real medication*

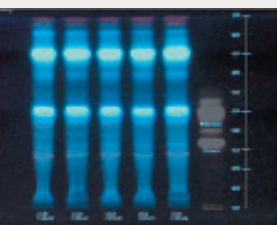
⁴ *The group of patients receiving the fake treatment*

Other clear results: a homeopathic complex remedy⁵ reduces an inflammation of the mucous membrane in the mouth (stomatitis) after chemotherapy; another complex remedy proves to be superior to the prescribed regular medicine with typical dizziness (vertigo); Aconite 4C reduces postoperative agitation in children by 75% compared to 32% treated with placebo.

In connection with a Swiss evaluation project on the social benefits of CAM treatments, the so called PEK project, a meta-study (Egger/Shang 2005) comparing 110 homeopathic study results with the same number of allopathic studies arrived at the heavily criticized conclusion that homeopathy was not better than placebo. As many other important studies showed the contrary, the PEK evaluators came to a positive position towards homeopathy and commented that meta-studies are not always unambiguous.

⁵ A composition of various usually low potency medicinal products

V. NOT JUST A DILUTION



Can a sip of water without even one molecule of another substance heal a sick person? The discussion surrounding homeopathy often concentrates on high dilutions, ignoring the importance of potentisation, one of the fundamental rules of homeopathy. Homeopathic medicines are not just diluted, they are also succussed, and it is the joint action which determines their potency. It would seem that water has the capacity to take on the information of the substance during the process of potentisation and retain this memory even if there is no material substance present.

"Everybody gets excited about those dilutions, but in homeopathy everything turns around the simile principle. Our research shows that a body-out-of-balance undertakes anything to retrieve its balance. That's fascinating! Why does nobody pick this up for further study?"

(Dr. Fred Wiegant, cell biologist, specialised in processes of self recovery)

The enigma of dilution

The most famous and at the same time the most notorious research project into the principles of homeopathy is the one by French scientist, Dr. Jacques Benveniste, published in 1988 in the influential magazine *Nature*. He noticed that basophile granulocytes produced histamine when they came in contact with a solution of certain antigens. A completely normal reaction, albeit that the solution was so extremely diluted that it was impossible that one single molecule of the antigen was left.

Half of the scientific world jumped on *Nature* and Benveniste. The set-up of the project seemed to be all right but the result was unacceptable. *Nature* repeated the experiment and accused Benveniste of committing fraud. He succeeded in having his second study published with the same results as in the first one and with strong indications for the mechanism of action - the simile principle⁶. In 2004 a European network of research centres participated in a multi-center trial which demonstrated that extreme dilutions of histamine activate human basophiles. This outcome is in line with what Benveniste discovered in 1988.

Extreme dilutions tend to be the reason for the major resistance against homeopathy. However, not all homeopaths prescribe those "infinite" dilutions. So why

⁶ *Simile: the medicine consists of a substance which invokes in a healthy person the symptoms of the illness*

do we have them? Hahnemann realised that he worked with potentially poisonous substances. He noticed that with high dilutions the side effects disappeared, leaving the desired healing effect unchanged. It is remarkable that from those solutions - of which we know today that they contain very few and in some cases not one single molecule of the original starting material - positive effects can nevertheless be noticed. All that brought us to daring theories. One of those theories is known as the "memory of water" which was already brought up during Benveniste's research projects. Water was said to be able to remember the imprint of a former contact with a substance and convey it at a later moment to other substances. In a more refined form this theory is known as the Information Medicine Hypothesis.

It is regrettable that sceptics tend to get entrenched in the problem of extreme dilutions. However, not all homeopaths work with it by any means. The dilutions beyond Avogadro's number do not belong exclusively to the "Constitution of Homeopathy". More important is the simile principle. The Dutch researchers Van Wijk and Wiegant demonstrated that this is a valid principle working at the cellular level. A minute quantity of a toxic substance (Cadmium) stimulates cells, damaged by a larger quantity of that very substance, to repair themselves.

And what about the so called potentising (shaking or succussion) during the dilution? Is it a ritual or does it add a value to the dilution? All practitioners confirm from their experience that potentisation is instrumental for the effectiveness. Does it have a plausible explanation?

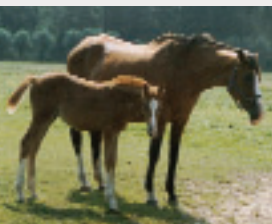
Researcher Fred Wiegant: "We are just about to understand that in the turbulence of liquids all kind of things happen with the properties of that liquid. We might find the explanation there."

Wiegant's former partner in research Van Wijk occupies himself, like the Swiss researcher Louis Rey among others, with thermoluminescence of extreme dilutions. Rey found out that solutions, which could not possibly contain a single molecule of the original starting material, produced - after radiation at very low temperature - the characteristics of the initially dissolved substance.

Science in this field - however carefully it may proceed - is in motion. However, the unexplained working mechanism is still a stumbling block between homeopathy and a considerable number of scientists. That is strange, since it is a good estimate that of fifty percent of the regular methods of treatment and medicinal products, the effect has not sufficiently been demonstrated or that no explanation of the working mechanism has been provided (Bower 1998). The aspirin tablet is a famous example. But the treatment and the product have found broad acceptance.

The distrust towards homeopathy does not quite fit the modern and pragmatic conception about medicine, requiring it to be first and foremost evidence-based. If it works it is useful, even if we don't have an explanation.

VI. ANIMALS HAVE NOTHING BETWEEN THE EARS



When a horse recovers from taking homeopathic medication, the success cannot be attributed to imagination or placebo effect. In researching homeopathic medicines on animals (and small children), complicated randomised, double blind studies do not seem appropriate. An animal does not speculate about its treatment. Hence, if a medicine works in veterinary use, it is effective.

"Veterinary homeopathy is cheap and effective. Equally important is the service rendered to food quality and environment in terms of safety – harmless medicines. In particular consumer organisations and environmental movements should have a more open eye for that..."

(Liesbeth Ellinger, President of the International Association of Veterinary Homeopaths)

A horse doesn't need a placebo

Homeopathy is a young branch on the tree of veterinary medicine. The success is so unequivocal and sometimes so spectacular that an increasing number of veterinarians use only homeopathy. You can't stop a bleeding artery or set a broken leg but complicated problems like inflammations, skin disorders, and even rheumatism, can be dealt with very well.

All over the world veterinarians specialise via a post graduate education in homeopathy, an education similar to the one followed by general practitioners. Like in orthodox medicine homeopathic principles are the same for both men and animals.

Systematic research into the effectiveness of veterinary homeopathy is relatively scarce and the outcome is not usually very impressive. How is that possible?

Liesbeth Ellinger is the President of the International Association of Veterinary Homeopaths. She does research herself and achieved remarkable results in the treatment of diarrhoea in calves. "...But not at every farm and certainly not at each farm with the same remedy. Most researchers did not take that into account and failed. Experienced farmers notice within an hour if a remedy is successful or not. When it is, then usually the problem is over the same day. With regular medicines we need three or maybe four days."

In one breath Ellinger sums up a number of important advantages of veterinary homeopathy. Homeopathy works quickly, it is animal friendly, relatively cheap and it can also be used - after some education - by lay persons. The latter is important for the Third World where only a few specialists are available to make a diagnosis. For homeopathy a diagnosis is not really required. What is needed is a list of symptoms as complete as possible. The former goes beyond the skills of an uneducated farmer, the latter falls very well within the scope of his abilities.

Although veterinary homeopathy is being practised all over the world, the main focus lies in Europe. During the time of the Cold War homeopathy was prohibited in Eastern Europe. Today the veterinarians are rapidly coming up to par. Great differences can also be noticed in Western Europe. In Sweden a veterinarian is not allowed to practice homeopathy but a lay person may do so. The United Kingdom has a long tradition supported by royal interest - and also Germany, Austria and Switzerland count quite a number of veterinary homeopaths. In Germany and Austria, where the number of animals per farm is lower as compared to The Netherlands, relatively more livestock is treated homeopathically.

On one hand, the European Directive 2001/82/EC even determines that in organic agriculture livestock preferably has to be treated with homeopathic or

phytotherapeutic medicinal products. On the other hand, a second more general Directive makes life very hard for veterinary homeopathy. Ellinger: "That's a pity. Animals and their owners enjoy the benefits from homeopathy... Animals also form an excellent basis for research. They have "nothing between their ears" so to speak, so when they recover it is not because of imagination or a placebo-effect." A number of recent studies confirm her opinion. The German Carstens Foundation collects research studies on CAM subjects . Of the 140 collected studies the scientist Schütte said, "According to the scientific data, considerable reduction of antibiotics used in food animal practice can be realised, as well as savings of other conventional drugs like anti-inflammatory products or hormone treatment."

Issautier and Filliat (1999) added four homeopathic medicinal products to the drinking water of more than 10.000 guinea fowl. Would it be possible to constrain contagious enteritis? The death rate in the verum group was considerably lower than in the placebo group (27:105, $P < 0.01$) Schütte himself tested a complex remedy against respiratory indications in intensively farmed pigs. In the homeopathy group significantly less animals fell sick compared with the placebo group and the group being offered the standard medication. Only a fourth group, those receiving high dose antibiotics, showed better results.

VII. EXPERIENCE BASED KNOWLEDGE, THE ANTHROPOSOPHIC APPROACH



Anthroposophic medicine shares the holistic approach with homeopathy and offers something over and above regular allopathic treatment. Medical care and medicines are attuned to the individual. Empirical science plays a key role. Because of that, scientific research according to common comparative standards becomes complicated. A new study design is being developed, allowing for the empirical component as well as the patient individuality.

Conventional physics and medicine are anchored in a particularistic – molecular, atomistic, local – reality principle; that is not the case with complementary medicine. Here lies the fundamental difference

(Dr. Helmut Kiene, "Komplementärmedizin – Schulmedizin")

The added value of the anthroposophic approach

'Regular, academic medicine, however, with an added value.' That is the description under which anthroposophic medicine feels most comfortable. The added value is the anthroposophic framework. It comprises the philosophy of which Rudolf Steiner is the spiritual father. Nowadays the added value is described as "what has become known about the aspects of human life, the soul and the spirit by means of research".

Regular medicinal products usually aim for the elimination of micro-organisms (antibiotics) and overruling physiological processes (hormone therapy). The anthroposophic medicinal approach addresses the capacities of self recovery.

With relatively few practitioners and patient-consumers, anthroposophic medicine is a considerable factor in the western medical setting. It offers its own health care institutions, within the formal health care system. A number of its medicinal products, including products for self-medication, are widely appreciated for their effectiveness. There is an international organisation, although practice is predominantly rooted in the German speaking countries and The Netherlands.

Anthroposophic doctors seek to involve the entire being of a patient in the treatment; including those difficult factors like life, soul and spirit. The medicinal products they have at their disposition serve the same purpose. They are medicinal products of vegetable and mineral origin where the plants have usually been grown and harvested in a special way. They have specific characteristics corresponding with those of the patient. In order to enhance these characteristics to their optimum, two crops are ploughed into the soil to nourish the third and final crop.

Similar to homeopathic medicine, anthroposophic medicines are diluted in order to exclude harmful side effects as much as possible as well as to achieve a more pin pointed effect. Anthroposophic medicinal products, however, are not usually as dilute as classical homeopathic medicinal products. Nevertheless, the fact that they are diluted means that they encounter the same objections from regular scientists as homeopathic medicinal products.

A second objection concerns the scientific foundation. Anthroposophic medicine can boast less recognised scientific research than homeopathic medicine, in particular RCTs⁷.

That deficit is a logical consequence of the nature of anthroposophy as a vision of life. That vision applies the term "experience based science"; which is a form

⁷ RCT: Randomised Clinical Trial, the golden standard for medical research in which disturbing real life factors and subjective judgements are excluded

of know-how which is considered as an extremely important addition to regular academic-scientific verification. Whereas nowadays established medical science bases itself in particular on Evidence Based Medicine⁸, in anthroposophic medicine the emphasis is on the individual judgement of the physician and the individual approach of the patient. This approach just doesn't fit in the structure of a RCT dealing with anonymous patients and averages.

The "experience based science" that anthroposophic medicine is working with is a term that is hard to define. It focuses on making applicable how the "experience expert" processes information - and all that in a reliable and controlled manner. We experience that phenomenon as "expertise" or "tacit knowledge", "skill" or "green fingers": like in chicken sexing where the expert flawlessly perceives if the one day old chicken is a hen or a rooster; or the experienced general practitioner who, by hearing a vague complaint, immediately knows whether it is "all right or not" or the oil expert who "feels" where a successful drill can be made. The know-how of such experts is based on experience. The fact that they often can't explain why doesn't diminish the value of it.

Presently anthroposophic institutions are making a great deal of effort to develop methods of research that both take into account the extraordinary

⁸ *Evidence Based Medicine: Medical interventions, based on knowledge supported by proven facts*

properties of anthroposophy and at the same time meet the acceptance of the academic scientific world.

In June 2005 a review was completed on all applicable studies into the effect and the cost effectiveness of anthroposophic medicine (Kienle 2004) in a peer reviewing process. The outcome will be made available at www.goetheanum-medizin.ch and www.ifaemm.de

Based on a systematic analysis of 178 scientific studies, a clear conclusion can be drawn: anthroposophic medicine is good, effective, safe and probably cost effective. In 170 studies the result was either a quicker or more convincing improvement of the patient by anthroposophic treatment compared with no or another treatment, or one could speak of total recovery or improvement of the symptoms.

The Swiss government - who initiated this study - is of the opinion that there is a sufficient indication of the usefulness and effectiveness of anthroposophic medicine. It has been concluded that in particular cancer patients need this kind of medical coaching and care. Taking into consideration the demographic development in Europe the Swiss government forecasts a considerable growth in demand for anthroposophic medicine.

A pilot study by the Dutch Louis Bolk Institute (Baars 2005) came to the conclusion that patients are highly

satisfied, especially about the individualised treatment. There are strong indications that the anthroposophic approach is cost effective. What makes this study even more interesting is that anthroposophic medicine scores well in dealing with the "top ten of complaints" responsible for the most significant part of the so-called burden of disease.

The anthroposophic interventions are considered by both the 40 general practitioners (80%) and the 399 patients (91%) as predominantly effective. The five indications where the doctors expect the strongest effect are: depression, anxiety, breast cancer, trauma and alcohol addiction.

This pilot study suggests that the burden of disease can be reduced considerably with anthroposophic medical assistance.

Anthroposophic medicine is aware that it is expected to come with verifiable proof. For that reason a great deal of effort is made to develop suitable methods of research which are recognised as valid by the regular scientific community. At the same time anthroposophic medicine is proud of the added value it offers regular medicine. Typical anthroposophic methods for diagnostics, choice of interventions and the evaluation of effects could serve regular medicine well. In this respect doubts are being more frequently and more openly expressed about the infallibility of the RCT and connected models.

CONCLUSION

Homeopathic and anthroposophic therapies are practised in all countries of the European Union. In most Member States these therapies occupy their own place beside the official (regular allopathic) medicine.

Both the European Union and the WHO are in favour of a full place of its own for homeopathy (and the related anthroposophic medicine) in the western system of regulated and controlled health care.

Science has provided the rationale. Some dozens of scientific studies have been characterised by friend and foe as impeccable. The best studies demonstrate that homeopathy has effect and that the effect cannot be attributed to a placebo effect. In some cases homeopathy scores even better than regular medicine.

In addition, the very good safety profile adds weight on the side of homeopathy. Undesired side effects and resistance building are very limited compared to allopathic medicine. In human medicine this is of a tremendous importance: antibiotics are gradually losing more and more of their efficacy. In veterinary medicine homeopathy contributes to improved food safety because milk and meat products can remain free from hormones and antibiotics.

However, research into homeopathy and its clinical possibilities is still in a developing stage. Prof. Stefan Willich, director of the Department of Social Medicine,

Epidemiology and Health Economics at Charité University Medical Center, Berlin: "There is an urgent need for controlled outcome studies assessing long-term effectiveness of patients treated with conventional versus complementary medicine. Apart from medication, the patient preferences and expectations, therapeutic setting, specific patient/physician relationship need to be considered and may contribute significantly to overall treatment effects".

REFERENCES

For this publication the following references have been consulted:

General

Baumgartner S, Thurneysen A, Heusser P. Growth Stimulation of Dwarf Peas (*Pisum sativum* L.) through Homeopathic Potencies of Plant Growth Substances. *Forsch Komplementärmed Klass Naturheilkd* 2004; 11: 281-292.

Khuda-Bukhsh AR. Towards understanding molecular mechanisms of action of homeopathic drugs: An overview. *Molecular and Cellular Biochemistry* 253: 339-345, 2003.

Lazarou J, Pomeranz B, Corey P. Incidence of adverse drug reactions in hospitalized patients. *JAMA* 1998; 279:1200-1205.

Website of prof. dr. Ivan Wolffers: (Artikelen/ Geneesmiddelenvoorlichting/Lessen over bijwerkingen) www.ivanwolffers.nl

Clinical research - homeopathy in humans; Reviews, Systematic reviews and Meta-analyses

Barnes J, Resch KL, Ernst E. Homeopathy for Postoperative Ileus? - A Meta-Analysis. *J Clin Gastroenterol* 25 (4), 1997: 628-633.

Bell IR, Lewis DA II, Brooks AJ, Schwartz GE, Lewis SE, Walsh BT, Baldwin CM. Improved clinical status in fibromyalgia patients treated with individualized

homeopathic remedies versus placebo. *Rheumatology* 2004; 1 of 6; 43(5): 577-582.

Jacobs J, Jonas WB, Jimenez-Perez M, Crothers D. Homeopathy for childhood diarrhea: combined results and metaanalysis from three randomized, controlled clinical trials. *Pediatr Infect Dis J* 22 (3), 2003: 229-234.

Kleijnen J, Knipschild P, ter Riet G. Clinical trials of homeopathy. *British Medical Journal* 302, 1991: 316-323.

Linde K, Clausius N, Ramirez G, Melchart D, Eitel F, Hedges LV, Jonas WB. Are the clinical effects of homoeopathy placebo effects? - A meta-analysis of placebo-controlled trials. *Lancet* 350, 1997: 834-843.

Oberbaum M, Yaniv I, Ben-Gal Y, *et al.* A randomized, controlled clinical trial of the homeopathic medicine TRAUMEEL S® in the treatment of chemotherapy-induced stomatitis in children undergoing stem cell transplantation. *Cancer* 2001, 92, 684-690

Taylor MA, Reilly D, Llewellyn-Jones RH, McSharry C, Aitchison TC. Randomised controlled trials of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *British Medical Journal* 321, 2000: 471-476.

Weatherley-Jones E, Nicholl JP, Thomas KJ, Parry GJ, McKendrick MW, Green ST, Stanley PhJ, Lynch SPJ. A randomised, controlled, triple-blind trial of the efficacy of homeopathic treatment for chronic fatigue syndrome. *J Psychosom Res* 56, 2004: 189-197.

Weiser M, Strösser W, Klein P. Homeopathic vs conventional treatment of vertigo - A randomized double-blind controlled clinical study. Arch Otolaryngol 124 (8), 1998: 879-885.

Wiesenauer M, Lüdtke. A Meta-analysis of the Homeopathic Treatment of Pollinosis with Galphimia glauca. Forsch Komplementärmed 1996; 3: 230-234.

Cost-Effectiveness studies

Unio Homoeopathica Belgica, An observational study of patients receiving homeopathic treatment (An observational study of 782 unselected patients receiving homeopathic treatment in Belgium from 80 general practitioners). Survey 2001.

Melchart D, Mitscherlich F, Amiet M, Eichenberger R, Koch P. Programm Evaluation Komplementärmedizin (PEK). Bundesamt für Gesundheit, Bern, Schlussbericht 2005. The PEK study is a type of outcomes research and uses components of well-established scientific disciplines such as epidemiology, clinical research, psychometrics, health economy and healthcare research. It is focused on perceived effectiveness.

Fundamental research

Belon P, Cumps J, Ennis M, Mannaioni PF, Roberfroid M, Sainte-Laudy J, Wiegant FAC. Histamine dilutions modulate basophil activation. Inflamm. res. 53, 2004: 181-188.

(Editorial in the same edition: Falus A. Homeopathy and high dilutions - is there a real effect? Inflamm. Res. 53 (2004) 179 - 180.)

Endler P.C., Lüdtke R., Heckmann C., Zausner C., Lassnig H., Scherer-Pongratz W., Haidvogel M., Frass M. Pretreatment with thyroxine (10-8 parts by weight) enhances a 'curative' effect of homeopathically prepared thyroxine (10-13) on lowland frogs. *Forsch Komplementärmed Klass Naturheilkd* 2003, 10: 137-142.

Rey L. Thermoluminescence of ultra-high dilutions of lithium chloride and sodium chloride. *Physica (A)*, 2003;323: 67-74.

Anthroposophic Research

Hamre HJ, Becker-Witt C, Glockmann A, Ziegler R, Willich SN, Kiene H. (2004). Anthroposophic therapies in chronic disease: the Anthroposophic Medicine Outcome Study (AMOS). *Eur J Med Res*. 30; 9 (7): 351-60.

Kienle, G. & Kiene, H. *Die Mistel in der Onkologie* (2003). Schattauer Verlag, Stuttgart, New York.

H.J. Hamre, H. Kiene, M. Fischer, M. Heger, D. Riley, M. Haidvogel, E. Baars, E. Bristol, M. Evans & R. Schwarz (2005). Anthroposophic versus conventional therapy of acute respiratory & ear infections: a prospective non-randomised comparative outcomes study. *Wiener Klinische Wochenschrift*, 117 (7/8).

Kienle, G.S., Kiene, H. & Albonico, H.U. (2004). Health Technology Assessment Bericht Anthroposophische Medizin. Programm Evaluation Komplementärmedizin (PEK) des Schweizer Bundesamtes für Sozialversicherung. Institut für angewandte Erkenntnistheorie und medizinische Methodologie.

E. Baars, R. Adriaansen-Tennekes & K. Eikmans (submitted). Safety of homeopathic injectables for subcutaneous administration as used in Homeopathic and Anthroposophic Medicine. *Journal of Alternative and Complementary Medicine*.

Alm JS, Swartz J, Bjorksten B, Engstrand L, Engstrom J, Kuhn I, Lilja G, Mollby R, Norin E, Pershagen G, Reinders C, Wreiber K, Scheynius A. An anthroposophic lifestyle and intestinal microflora in infancy. *Pediatr Allergy Immunol*. 2002 Dez; 13(6): 402-11.

Alm JS, Swartz J, Lilja G, Scheynius A, Pershagen G. Atopy in children of families with an anthroposophic lifestyle. *Lancet* 1999; May 1; 353(9163): 1457-8.

Veterinary Research

R. Searcy, O. Reyes, G. Guajardo. Control of subclinical bovine mastitis. *British Hom J* 1995 Vol. 84 67-70.

CH Sandoval, LL Morfin, BB Lopez. Preliminary research for testing *Baptisia tinctoria* 30c effectiveness against salmonellosis in first and second quality broiler chickens. *British Hom J* 1998 Vol. 87 131-134.

See also:

www.carstens-stiftung.de

www.goetheanum-medicin.ch

*"Scepticism may be a good attitude for a scientist,
but the Universe is vast and still keeps many things secret.
So a good scientist has to free himself
of fixed concepts and dogmatism,
keeping sharp eyes and an open mind."*