

Desk study on homeopathy in organic livestock farming

Principles, obstacles and recommendations for
practice and research

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CONTENTS

SAMENVATTING	3
SUMMARY	4
1. INTRODUCTION: A DIFFERENT HEALTH AND WELFARE CONCEPT?.....	5
2. POTENTISED REMEDIES: THE DIFFERENT SCHOOLS OF THOUGHT.....	8
3. OBSTACLES TO HOMEOPATHY: SCIENTIFIC AND CONCEPTUAL	11
3.1. OBSTACLE TO CORE RESEARCH: CLINICAL TESTING OF HOMEOPATHY.....	11
3.1.1. <i>Systematic reviews</i>	12
3.1.2. <i>Evaluation of recent unreviewed outcome studies</i>	12
3.1.3. <i>Conclusion</i>	14
3.2. OBSTACLE TO CORE RESEARCH: EVIDENCE FOR THE SIMILIA LAW	15
3.3. OBSTACLE TO CORE RESEARCH: EFFICACY OF HIGH DILUTIONS	15
3.4. PRACTICE DEVELOPMENT RESEARCH.....	16
3.4.1. <i>The method of choosing a therapy</i>	16
3.5. OBSTACLES TO PRACTICE DEVELOPMENT RESEARCH	17
3.6. OBSTACLES TO SUPPORTING RESEARCH IN HOMEOPATHY.....	18
3.6.1. <i>Obstacle to supporting research: causality arguments</i>	18
3.6.2. <i>Obstacle to supporting research: ontological reductionism</i>	19
3.6.3. <i>Obstacles to supporting research: arguments concerning therapeutic effect</i>	22
3.6.4. <i>Obstacles to supporting research: placebo-effect</i>	22
3.7. CONCLUSION, SUPPORTING RESEARCH: FAILURE OF ONTOLOGICAL REDUCTIONISM	23
4. OBSTACLES TO VETERINARY HOMEOPATHY: PRACTICAL AND LEGAL	25
5. SOLUTIONS TO OBSTACLES.....	27
5.1. DOUBTS CONCERNING EFFICACY	27
5.2. METHODOLOGY FOR CLINICAL TRIALS	27
5.3. INDIVIDUAL NATURE OF HOMEOPATHIC TREATMENT.....	27
5.4. INCORPORATING EXPERIENTIAL KNOWLEDGE	27
5.5. NEED FOR SUPPLEMENTARY OUTCOME EVALUATIONS	28
5.5.1. <i>Randomised Clinical Trial versus Therapeutic Causality Report</i>	28
5.5.2. <i>Scientific underpinning of TCR</i>	30
5.5.3. <i>Causality in RCT and TCR</i>	31
5.5.4. <i>Research design to determine the effects of homeopathic treatment</i>	32
5.6. BEYOND THE BOUNDS OF MATTER	33
5.7. PRIOR TESTING OF QUALITY OR POTENTIAL EFFICACY OF THE REMEDY.....	33
5.8. DEVELOPING A RESEARCH INFRASTRUCTURE IN THE NETHERLANDS.....	33
5.9. DEVELOPMENT OF VOCATIONAL TRAINING IN VETERINARY MEDICINE.....	34
6. CONCLUSIONS AND RECOMMENDATIONS	35
7. REFERENCES.....	37

Samenvatting

De acceptatie van homeopathische middelen is beperkt ondanks het feit, dat er enig empirisch bewijs is voor de werkzaamheid van homeopathische behandelingen. Vanuit de wetenschap is er echter een afwijzing vooraf op basis van ontologische gronden en het veronderstelde werkingsmechanisme. Vervolgonderzoek naar homeopathische middelen is nodig, maar dient aan te sluiten bij het achterliggende complementaire gezondheids- en welzijnsconcept van de biologische veehouderij. Het gebruik van Randomised Clinical Trials is slechts in beperkte mate wenselijk, omdat hierdoor het individualiserende karakter van de behandeling buiten spel gezet wordt. Er zijn echter voldoende alternatieve methodologiën ontwikkeld die bij het effectonderzoek gebruikt kunnen worden. De onderzoekers stellen een stapsgewijze opbouw van het effectonderzoek voor, waarbij als eerste aansluiting wordt gezocht bij het monitoren van ervaringen in de praktijk, wat gevolgd wordt door casuïstisch effect onderzoek.

Summary

Organic livestock farming has its own concept of health and welfare. The approach to health can be characterised by the key words human, preventive, self-regulating and holistic (Chapter 1). This has consequences for the way we deal with diseases and problems, the nature of the solutions and the use of medication, among other things. In terms of therapeutic and regulatory measures this health concept is based primarily on natural food supplements and homeopathic remedies, which in view of their origin fit in well with the natural character of organic agriculture (Verhoog *et al.*, 2002). Apart from various forms of potentised remedies (classic, clinical, anthroposophic, isopathic; Chapter 2) and all manner of applications within phytotherapy (Bach flower, aromatherapy), there is interest in organic livestock farming in complementary health treatments other than acupuncture. We also need more detailed research into the practical implications of possible self-medication by animals (Engel, 2001).

Complementary medicine demands a new type of knowledge in relation to its working mechanism, testing for authenticity and the way it is used (Chapter 3). The thinking behind the use of homeopathic remedies often based on a preventive approach to health. With the aid of these remedies the doctor seeks to create a more balanced environment in and around the animal and to improve the animal's resistance to infections (Baars en Ellinger, 1997). Striezel (2001) calls homeopathy a regulatory therapy, which heals the body by stimulating the individual immune system and regulating the metabolism. The use of homeopathic remedies is still limited in practice, partly due to a lack of suitably trained veterinary practitioners (Chapter 4). In the elaboration of the research questions the authors discovered that the use of homeopathic remedies meets with particular resistance which can be traced back to philosophical assumptions (sections 4.1-4.3). As the research is fleshed out it is therefore important that it is not simply carried out in conformity with currently valid scientific standards. The research design must also be in line with the philosophy of homeopathy in terms of both quantity and quality (Chapter 5). This is particularly important for homeopathy because its therapeutic methods are based on principles which do not fit in with conventional notions about life. The similia principle (law of similars) is an important feature of homeopathy¹ and homeopathy shares the second key concept of potentisation with anthroposophy (Chapter 2).

There is limited acceptance of homeopathic remedies in particular, despite the fact that there is some empirical evidence for the efficacy of homeopathic treatments. Both **outcome research** into homeopathic treatments of humans and animals and fundamental empirical research into the validity of the similia law and the efficacy of high dilutions produce results which tend to bear this out. However, it is rejected out of hand on ontological grounds and because of the assumed working mechanism.

Follow-up research into homeopathic remedies is desirable, but must be in line with the underlying complementary health and welfare concept of organic agriculture, which includes treatment with veterinary medicines. Randomised Clinical Trials are thus only of limited use, since they disregard the individually tailored nature of the treatment. In practice however, sufficient alternative therapies have been developed which can be used in outcome research. The researchers propose a graduated structure for the **outcome research** (Chapter 6). The first step is to join in with the monitoring of experience in practice, and follow this with **casuistic outcome research**.

¹ In this desk study various therapies are referred to in Chapter 2 which are based on the use of potentised substances. Despite the fact that homeopathic remedies have their own interpretation and background, we also use this designation as a sort of umbrella term for the various movements or schools which have potentisation in common.

1. Introduction: a different health and welfare concept?

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Organic agriculture more or less explicitly uses health and welfare concepts which differ from generally accepted views (Baars and Buitink, 1995; De Jonge and Goewie, 2000; Hovi and Vaarst, 2001). These concepts can be regarded as complementary and are based on: (1) supporting and caring for natural behaviour as an expression of integrity (2) coherent, preventive farm management aimed at prevention of diseases and problems and (3) the use of 'alternative' medication and therapies.

In conventional (veterinary) medicine illness is often seen as a lesion: a demonstrable abnormality in an organ, tissue, cell or DNA structure. Health is accordingly defined in terms of the absence of such lesions. Treatment of diseases is logically often aimed at removing the symptoms of diseases or their immediate cause with the aim of restoring the original structures and relationships. Conventional medicine and interventions in this case include the administration of chemical preparations, operation or radiation. Even in complementary forms of medicine it is not denied that various illnesses, certainly in their final stages, often show evidence of abnormalities. However, the difference is that the abnormality is not seen as the disease itself, but as a consequence of the imbalance between the various parts or subfunctions within the animal or person and their environment. From this point of view these abnormalities are only the external symptoms of the actual problem which the doctor or therapist must address (restore balance), rather than simply removing or suppressing the external symptoms (Aakster, 2001).

We can distinguish three different strands within this complementary concept of health and welfare in organic livestock farming itself (Verhoog *et al*, 2002). Each has its own views about approaches to sickness and health according to certain principles.

- (1) In the '*no chemical approach*' the ideas do not stray far from conventional thought and action. However, in place of synthetic chemical remedies there is a demand for natural remedies which do not require change in the system of production. The general desire for 'alternative medicines' fits in well with this view. In principle people still mainly respond symptomatically by combating the symptoms of disease.
- (2) In the '*agri-ecological approach*' thinking is directed towards reinforcement of the natural (ecological) processes. The idea of a balanced (agri-) ecosystem, which includes self-regulating feedback principles, serves as an model for good practice. In relation to sickness and health there is a strong orientation towards prevention – preventing disease in conjunction with adapted management. The pathogen is no longer a synonym for the disease. Instead attention is turned to the context of diseases and problems which have to do with the way the farm is operated. Managerial changes in feeding, housing and in the longer term also breeding and selection regimes must lead to better harmonisation of animal production with the capacity and potential of each agri-ecological environment.
- (3) In the third approach the thinking centres on '*integrity*'. Here people base their actions on the concept of the integrity of the animal and also that of the disease. In this approach the moral component is expressed in a different way to the agri-ecological approach, which focuses on good technical functioning of the system. Here the farmer has an influential role in relation to the needs of his livestock in terms of singularity and entity. Concepts such as 'empathising with' and 'eliciting from' belong to this approach. This can be specifically expressed in the choice of breeding and selection methods, respecting the animals' natural behaviour, the housing of the animals and other arrangements on the farm. In its approach to sickness and health, it is in tune with the concepts of homeostasis as well as self-regulation and self-medication. In addition to knowledge on the ecological conditions for optimum animal production, ('hard system approach' in agro-ecology) the attitude, knowledge and experience of the farmer ('soft side of knowledge'), are extremely important, and this is manifest in the relationship between man and animal (Seabrook, 2000; Baars and Brands, 1999; Hemsworth and Coleman, 1998; Waiblinger *et al.*, 2000). The experienced eye of the stockman and an attitude of respect for the intrinsic value of his animals are important factors in the development of early diagnosis and intervention tailored to the needs of each individual animal. This is not only important in terms of welfare (Bestman,

2002; Baars en Brands, 2000; Waiblinger and Menke, 1999): early diagnosis of farm-based disease and problems is also very important.

Practical examples of the application of complementary health concepts

Over the years various aspects of the health concept referred to here have been developed and used in practice. For example, the veterinary practitioner Spranger served German and Danish organic farms so well that in due course his role as a veterinary practitioner became 'surplus to requirements'. In his guidance to farms he emphasised stimulating self-regulation by the animals and the farm system, among other things by paying more attention to nutrition, housing, chain control and the closed nature of the system, and ways of dealing with animals and breeding (Spranger, *mond.med.*, 1995). Recently there have been initiatives for the introduction of 'organic animal health planners' (Gray and Hovi, 2001; Vaarst *et al.*, 2001; Eysker, 2001). Within organic livestock farming there is a surge of interest in the importance of minerals, trace elements and vitamins in the prevention of disease and restoration of health (Baars and Opdam, 1998; Barkema, 1998). MacNaiedhe (2001) demonstrated the significant differences in concentrations of mineral and trace elements in the various grassland plants. Herbaceous plants and clovers have a different, often higher, concentration of trace elements (e.g. Cu and Se) than species of grass.

In Dutch livestock farming practice there is greatly increasing interest in the use of homeopathic remedies which the farmers can apply themselves on the farm. A basic homeopathy course can greatly improve the farmer's ability to recognise symptoms from a homeopathic perspective (Ellinger, *mond.med.*, 2002). British research (Hovi and Roderick, 2000) indicated that 51% of mastitis treatments on organic farms were homeopathic, compared with 41% with antibiotics. On conventional farms all treatments are with antibiotics. During a workshop of the Network for Animal Health and Welfare in Organic Agriculture (Hovi and Vaarst, 2001) a series of research papers was presented on the use of homeopathic remedies in livestock farming. Organic livestock farmers are very interested in different types and species of animal on their farms. Dairy farmers are expressing an interest in breeding animals which are better-balanced and better able to achieve good production on fodder-rich rations (Nauta *et al.*, 2002, in preparation).

Books have recently appeared on self-medication by animals, as part and parcel of their natural behaviour (Engel, 2001; Thoresen, 2001). At the same time there is increasing demand for 'old knowledge and experience'. The far-reaching industrialisation of food production raises the issue of how much 'indigenous and tacit knowledge' is still available in practice to flesh out a more holistic approach to health. Such valuable knowledge still exists in some places, such as the Caribbean. Lans (2001) recently obtained his doctorate with a thesis on the use of ethno-veterinary treatments in animals. Her study shows that much experiential knowledge of human and animal herbal medicine is passed down from generation to generation. Engel (2001) also shows that in Africa and elsewhere much experiential knowledge is used in the phytotherapeutic treatment of humans and animals. An international network of anthropologists, agronomists and veterinary practitioners is in the process of documenting this traditional knowledge (McCorkle *et al.*, 1996). There has as yet been only scant scientific evaluation of the effect of the herbs used. The development of adequate prevention strategies requires autoecological and synecological knowledge of pathogens, in order to understand how infection cycles can be broken. Thamsbourg (2001) looks in detail at the epidemiology of gastrointestinal parasites in sheep and the possibilities and limitations of prevention. Significant elements of the prevention strategy include: repeated movement to fresh pasture; availability of sufficient supplementary feed and a herd density matched to crop production capacity. However, even he admits that supplementary measures are required to reach real long-term solutions: use of fungi which regulate nematodes, bioactive feeds (rich in **secondary plant substances**) and adapted animal breeding and selection programmes.

Medicines which are compatible with organic livestock farming

Under European legislation organically farmed animals must where possible be treated with homeopathic or phytotherapeutic remedies. If an animal is treated with **chemically synthesised medicines** a double **withdrawal period must be observed**. A rule in force since August 2001 states that if an animal is treated more than twice per year with **chemically synthesised medicines**, the products of that animal may no longer be sold on the organic market (EC Regulation No 2092/91). SKAL, the inspection body for organic agriculture in the Netherlands has adopted these rules. Thus on the grounds of both principle and standardisation there is considerable interest in the development of alternatives in organic livestock farming.

As regards therapeutic and regulatory medicines the complementary health concepts are mainly supported by natural food supplements, and homeopathic and phytotherapeutic remedies. Given their origin these go well with the natural character of organic agriculture (Verhoog *et al.*, 2002). In addition their (supposed) working mechanism is compatible with the complementary health approach. With the aid of these remedies the practitioner is specifically looking to provide a more balanced environment in and around the animal and to increase the animal's resistance to infections (Baars and Ellinger, 1997). Striezel (2001) for example calls homeopathy a regulatory therapy, which heals the body by stimulating its own immune system and regulating its metabolism. Apart from different forms of potentised remedies (classic, clinical, anthroposophical, isopathic; see Chapter 4) and all manner of applications using phytotherapy (Bach flower, aromatherapy), there is interest in organic livestock farming in other complementary medical treatment methods other than, for example, acupuncture.

Evidence-based use of non-chemical medicines in organic livestock farming

The complementary medicine approach is growing in organic livestock farming practice (Hovi and Vaarst, 2002). However there is also a degree of scepticism among many 'unbelieving' scientists, veterinary practitioners, farmers and market gardeners. If this approach is to be 'evidence-based' and lead to greater acceptance, it will be necessary to pay scientific attention to the validity of the working mechanism, scientific testing for efficacy and quality of treatments and the way the quality and efficacy of the approach can be optimised in practice (see also Schütte, 1994).

Objectives of the desk study

The growing market for organic food is accompanied by a desire on the part of the government to reduce the use of various chemical pharmacological medicines in livestock farming for reasons of toxicity, environmental residues and eventual resistance. The organic livestock farming sector specifically wants to use medicines which are compatible with its own health concept. These two elements together were the incentive to catalogue what is known about the use of homeopathic remedies in organic livestock farming. The primary objective of this desk study is therefore to provide an overview of existing research in homeopathy, in terms of both results and methodologies. A secondary objective is to provide insight into the way in which new research could be carried out into the use and efficacy of homeopathic remedies in organic livestock farming.

Before going on to evaluate the way such research is designed, we will consider the problems affecting research on homeopathic remedies.

2. Potentised remedies: the different schools of thought

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Figure 1 (Riedel-Caspari, 2000) shows a view of the relationship between synthesised preparations (modern pharmacology), phytotherapeutic preparations, foodstuffs and potentised remedies. Many pharmaceutical products are isolated from natural substances and are offered as pure substances which may or may not have been chemically synthesised. Various medicines have already been developed from many plant materials. Examples include aspirin as an analgesic, terpenoids which suppress tumour growth, and taxol, used in the treatment of leukaemia.

- I. Isolated plant materials (chemically pure)
- II. Potentised substances based on plant tinctures
- III. Seasonings and flavourings (foods)

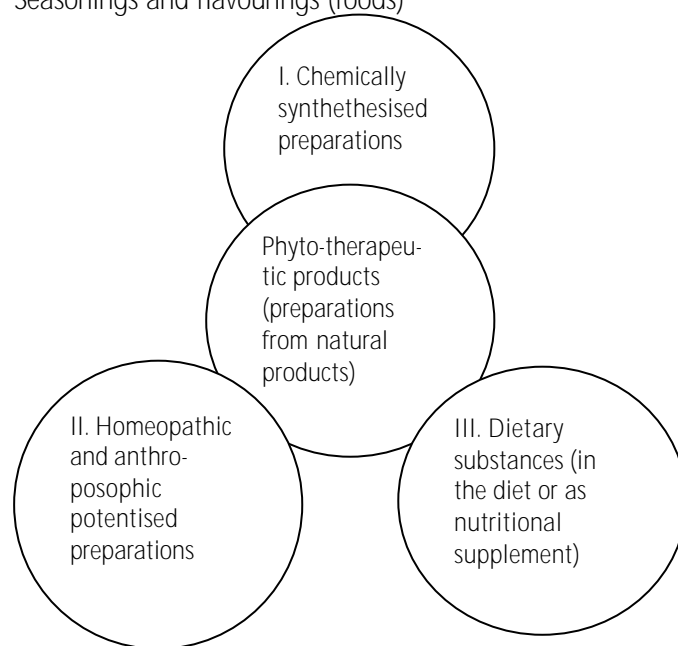


Figure 1. The relationship between phytotherapeutic, homeopathic, chemical-synthetic preparations and nutritional supplements (Riedel-Caspari, 2000).

Compared with phytotherapy, the methods of homeopathy, anthroposophical medicine and allopathic medicine have only been in existence for a short time. Phytotherapy, also commonly called herbalism, is a traditional method of healing using various plant preparations as medicines. The working mechanism underlying the effect, particularly in chemical terms, was unknown several centuries ago. Only later, when knowledge of chemistry grew was it discovered that the effect of phytotherapeutic substances (plant extracts) was based on the activity of several substances, namely the supposed pharmaceutical products (main active ingredients), accompanying substances, which can be responsible for accompanying effects and the ballast substances, which are assumed to have no pharmacological effect. The main active ingredients, together with the accompanying ingredients, form the bioactive components of the plant. Phytotherapy has laid a very important basis for modern pharmacotherapy, since many of the chemical compounds used as medicines are extracted from plants. Thus there is no difference in principle between modern pharmacotherapy and

phytotherapy, except that in phytotherapy more substances are administered than the pure chemical active ingredient. Both therapeutic methods can be used in a symptom-oriented approach, which is concerned with making a diagnosis of an illness. From this, thinking in causal chemical relationships, treatment is instigated which both in folk and conventional medicine leads to the selection of a remedy which is independent of the patient and other factors. Many phytotherapeutics are however also used in the context of traditional medicine, in which patient-specific differentiations are made. The working mechanism of phytotherapeutics can be understood in a material context and is sometimes investigated to the level of the molecules which form an association with molecules in the body. In the case of many homeopathic remedies this material model cannot explain the working mechanism. It is impossible, according to pharmacologists, that following potentisation² there is still a molecule of the original substance present in the product. This is because dilutions greater than 10⁻²³ exceed the Avogadro number. This brings us directly to a problem in the relationship between homeopathy and conventional medicine. How is it possible for a substance to be active if it does not contain any molecules of the diluted natural substance? And that is not all: homeopathy also uses substances based on the similia principle (**like cures like**), which is at odds with the symptom-based approach of conventional medicine.

The principle of homeopathy (homoios = like, pathos = suffering) dates from the 18th century and was developed by German doctor Samuel Hahnemann. However, when it comes to the principle of similia similibus curentur Hahnemann refers to Hippocrates, who wrote: *Sickness is caused by similar stimuli and sickness can be cured by similar stimuli*. Hahnemann discovered that the symptoms caused by taking an undiluted substance (animal vegetable or mineral), can be compensated or cured by taking the same substance as a dilute solution which has been potentised. Hahnemann accurately and systematically studied the effects of many substances which he administered to healthy people. This gave him a picture of which symptoms the substance could be used to treat following potentisation. These "symptom pictures" still form the basis of homeopathy today. Potentisation did not reduce but rather increased the effect of the remedy. Thus it was possible to create an active substance from substances which otherwise had little or no effect.

Different schools have grown up within homeopathy: classic homeopathy, clinical homeopathy and isopathy. Classic homeopaths apply homeopathy in its most original form. The doctor tries to determine the nature (constitution) of the person by asking questions. With the aid of 'constitutional remedies' the practitioner aims to improve the overall condition of the patient and to improve his or her resistance. In this form of homeopathy the whole person as an entity is central.

Clinical homeopathy takes a more symptom-oriented approach. The practitioner is looking for a remedy which corresponds more with the symptoms of the illness than with the general symptoms of the patient. It is not the whole patient but the illness which is central. And finally there is isopathy. This form of homeopathy uses not a 'like' substance, but *the same* substance, albeit potentised, to restore the balance. The products of the illness itself or of the patient himself are given back to the patient - possibly in potentised form - (for example saliva for rabies, pus for an abscess or their own milk for mastitis).

Hahnemann wrote in his *Organon*: *"We will never fathom the cause of disease; an attitude which is no longer acceptable in our time. We need insight into the fact that a remedy potentised to the point of immateriality is effective"*. These issues were taken up by Rudolf Steiner who tried to clarify the background against which homeopathic principles can be understood. Steiner indicated that the aim of potentisation was to activate the hidden forces in the substance rather than the chemical substances. Just as in homeopathy the picture of a remedy is sought in a symptom picture of the disease, so in anthroposophical medicine one tries to understand the disease picture from a particular human picture. Aspects which play an important role in the anthroposophical human picture are the threefold nature of the human organism (upper pole, lower pole and central region) and the construction of a human being in four "bodies": the **physical body**, the **etheric body**, the **astral body** and the **Ego**. Processes are examined and pictures are created of the disease process and the patient, then remedies are sought which set comparable processes in train or conversely, counter them. One of the keys to recognising these corresponding processes lies in the principle of three-foldness. The same division into three parts can be recognised in both humans and plants. This clearly points up a distinction between homeopathy and anthroposophy. Anthroposophy focuses less on the symptoms than homeopathy,

² Potentisation is the gradual dilution and (rhythmical) agitation of an original substance.

focusing rather on the processes which lead to the symptoms. Also, while potentiation is an important method of preparing remedies in anthroposophy, unlike in homeopathy, it is not the only one. Anthroposophical medicine also includes warmth treatments in which the place on which the remedy acts changes as well as the composition of the remedy. Likewise the principle of 'the same' becomes, through 'similar' healing, one of the principles in anthroposophical medicine. For example it is also possible to treat a disease process with exactly the opposite. Finally there is a difference in the use of high potencies. In homeopathy very high potencies such as C1000 or LM18³ are not uncommon, whereas in anthroposophical medicine these high dilutions are not prepared because of the impressive strength. The assumption is that the treatment is not likely to be as coercive as is sometimes the case with commercial biochemical medicines.

The above arguments show that while homeopathy and anthroposophy share the principle of potentiation, they implement it differently. Ultimately we can conclude that homeopathy, anthroposophy and natural medical phytotherapy are each very individual branches of medicine and that the phytotherapeutics they use are on the way to gaining a place in conventional pharmacotherapy.

Having discussed the various schools of thought, we proceed in the next chapter to scientific problems in relation to the use of homeopathic remedies.

³ Dilution and potentiation can be performed in stages of 1:10 (D-potency), 1:100 (C- potency) or, for example, 1:50,000 (LM- potency)

3. Obstacles to homeopathy: scientific and conceptual

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The current approach to animal health raises various problems of a scientific nature which stand in the way of determining the possibilities and impossibilities of homeopathic treatments in animal health within organic agriculture and (the further development of) their responsible use.

Kramers (1998) distinguishes three clusters of research activities in the field of homeopathy:

- Core research (relates to evaluation of empirical research),
- Practice development research (relates to development in practice) and
- Supporting research (relates to evaluation of adjoining research).

Core research, according to Kramers, encompasses five areas, namely:

- Drug tests (proving): research in which – at non-toxic level – certain substances are tested on healthy volunteers to observe as many effects as possible,
- Validity of the similia principle,
- Efficacy of the ‘high dilutions’,
- Clinical testing of homeopathic remedies, and
- Cost-effectiveness studies.

The second cluster, the *practice development research*, aims to improve the quality and thus also the professionalism of homeopathic practice (professional practice). The third cluster, *supporting research*, is there for the benefit of the first cluster and relates to research activities which can contribute to greater insight into certain phenomena, such as self-recovery and the placebo effect, which play an important role in medicine, including homeopathy.

Within all three of the clusters there are problems which hamper the use of homeopathic treatments in practice in organic agriculture. In this chapter some of the major problems in each cluster are discussed. With regard to the first cluster ‘core research’ we discuss clinical testing of homeopathic remedies, the validity of the similia principle, testing the quality of remedies and the operation and efficacy of ‘high dilutions’. With regard to ‘practice development research’ we will look at the problems arising from the sometimes complex practice of homeopathic treatment, such as the profiling of the patient, the time aspect of the successive treatments and the role played by experiential science. The problems arising in the cluster of ‘supporting research’ are the scientific value of the concepts of self-recovery and the placebo effect and the validity of the underlying theoretical model of holism (versus reductionism).

Chapter 6 contains recommendations for solving the scientific and conceptual problems.

3.1. Obstacle to core research: clinical testing of homeopathy

One of the first problems in responsible application of homeopathic veterinary treatments lies in the fact that there is still some doubt among farmers, veterinary practitioners and policy-makers concerning the efficacy of these treatments. Evaluation of the effect of homeopathic treatments focuses on the two following questions:

- What are the empirical elements of the evidence that homeopathy is effective?
- What results of outcome research show that there is an association between homeopathic treatment and any subsequent effect?

In the past few decades the method of systematic review has been developed to analyse the results of several outcome trials at metalevel. The quality of the trials is analysed on the basis of the methodology and

statistics used. Thus a statement can be made about each trial as to whether there are distortions ('bias'). In this way, using all the available information from all the outcome trials it is possible to decide whether there is an association between experimental intervention and a subsequent effect, and if so, how great the effect is estimated to be.

Several studies have been carried out in recent years into the effect of homeopathic treatments. A number of reviews of studies are summarised below with an overview of some more recent studies on homeopathy. These latter studies are also evaluated for quality according to criteria such as those adopted by, among others, the Cochrane Collaboration, an institute working internationally on the implementation of systematic reviews and improving their quality. Finally, based on the reviews and the overview, we come to a conclusion on the issue of whether there is sufficient empirical evidence to assume a demonstrated association between homeopathic treatment and subsequent effect.

3.1.1. Systematic reviews

Despite the fairly general observation that many research projects lack methodological quality, (Kleijnen *et al.*, 1991; Linde *et al.*, 2001), four articles were found in which the effect of homeopathic treatment of animals (one) and humans (three) was investigated by means of a meta-analysis.

After an analysis of the literature on homeopathic treatment of animals, Schofield (1984) concluded: *'It is obvious from this review that, despite much experimental and clinical work, there is only a little evidence to suggest that homeopathy is effective. This is because of bad design, execution, reporting, analysis and, particularly, failure to repeat promising experimental work and not necessarily because of the inefficacy of the system which has yet to be properly tested on a large enough scale. There is sufficient evidence to warrant the execution of well designed, carefully-controlled experiments to investigate the efficacy of homeopathy further.'*

Based on an analysis of 105 trials Kleijnen *et al.* (1991) concluded that on the one hand the evidence of clinical trials is positive, but on the other hand is inadequate to draw definitive conclusions. The reasons are the poor methodological quality of the majority of trials and the unknown role of possible publication bias: (in other words where potentially negative results of trials are not published). The authors argue that there is a valid case for further evaluation of homeopathy, but that it should be based on trials of good methodological quality. Based on a meta-analysis of 89 studies, Linde *et al.* (1997; 1999) concluded that the results cannot be reconciled with the hypothesis that the clinical effects of homeopathy can be wholly attributed to a placebo effect. However, they find insufficient evidence that homeopathy is clearly effective for any clinical indication. These authors also raise the issues of publication bias and the poor methodological quality of most studies. Finally, Cucherat *et al.* (2000), examined 17 trials and concluded that there is some evidence that homeopathic treatments are more effective than a placebo. However, the authors maintain the evidence is weak since the trials are often of poor methodological quality. The studies of a higher methodological quality were also more likely to produce a negative result than the low quality studies.

3.1.2. Evaluation of recent unreviewed outcome studies

Since the publication of the review articles, many publications have appeared on outcome trials of homeopathic treatments of humans and animals. We analysed a series of articles which were obtained through research institutes, PubMed and homeopathic pharmaceutical industries and subsequently 'the snowball method'. (Tables 4.1 and 4.2).

One striking result of the analysis is that practically all the trials are of inadequate quality and there is thus a high risk of bias or distortion in every study. Only one of the trials was of moderate quality. Ten of the sixteen trials claim a statistically significant improvement: one of these was the only study of moderate quality.

Table 4.1. Overview of various human homeopathic trials and the evaluation of the quality of the trial based on the criteria of the Cochrane Collaboration

Trial	Research group	Intervention	Type of research ¹⁾	Primary outcome standards	Result	Quality of research ²⁾
Chapman (1999)	Patients with MTBI (N=50)	Various homeopathic preparations 4 months	RCT	SRS, DSS, PDAS *	Significant difference	moderate
Taylor (2000)	Patients with seasonal allergic rhinitis (N=50)	Homeopathic dilution of primary allergen Preventive 4 weeks	RCT	1. Nasal inspiratory peak flow (NIP) 2. Visual analogous scale (subjective)	NIP sign. difference (p=0.0001) no sign. VAS	inadequate
Balzarini (2000)	Patients operated for breast cancer with radiation therapy (N=61)	Belladonna 7 cH, X-ray 15 cH 8 weeks	RCT	TSI RTSI**	TSI not sign. RTSI sign. (p=0.05)	inadequate
Van Haselen (2000)	Osteoarthritis knee (N=184)	SRL® gel vs. Piroxicam gel 4 weeks	RCT	1. pain in walking/ to touch (VAS)	Not sign.	inadequate
Jacobs (2000)	Acute diarrhoea (N=116)	Individual homeopathic medicine vs. Placebo Maximum 5 days	RCT	1. diarrhoea Index-score	Sign. Improvement (p=0.05)	inadequate
Stam (2001)	Acute lower back pain (N=21)	SRL gel vs. CCC●● 7 days	RCT	1. intensity of pain (VAS, subjective)	N to low for analysis	inadequate
Yakir (2001)	Women with pre-menstrual syndrome	Individually tailored homeopathic dilution	RCT	MDQ***	Strong improvement in symptoms compared with placebo	inadequate
¹⁾ RCT = randomised clinical trial Q. exp. = quasi experimental research Coh. = Cohort						
²⁾ Research was evaluated in accordance with the Cochrane Collaboration (inadequate = high risk of bias, moderate = moderate risk of bias, adequate = low risk of bias)						
● MTBI = Mild traumatic brain injury ●● CCC = Cremor Capsici Compositus FNA						
* SRS = Symptom Rating Scale DSS = Difficulty in Situations Scale PDAS = Participation in Daily Activities Scale ; all three scales for evaluation of function ** TSI = Index of Total Severity during Radiotherapy (skin); RTSI = Index of Total Severity during Recovery (skin) *** MDQ = menstrual distress questionnaire						

Table 4.2. Overview of various veterinary homeopathic trials and the evaluation of the quality of the trial based on the criteria of the Cochrane Collaboration

Trial	Research group	Intervention	Type of research ¹⁾	Primary outcome standards	Result	Quality of research ²⁾
Day (1986)	Heifers (N=7)	Preventive use of Caulophyllum 30c Unknown	Case study	Dystokia	Improvement	Inadequate
Day (1986)	Dairy cows (N=82)	Mastitis nosode 30c vs. Placebo 9 months	Q. exp.	Cell count Diagnosis mastitis	Nosode greater effect. No statistical processing	Inadequate
Van Rooy (1990)	Dairy cows (N=28)	Nosode therapy 20 days		Mastitis	No clear effect	Inadequate
Stopes (1990)	Dairy cows (N=?)	Nosode therapy 18 months	Q. exp.	Mastitis	No clear effect	Inadequate
Egan (1995)	Dairy cows (N=15)	Oral homeopathic preparation + massage with homeopathic preparation 17 days	Q. exp.	Subclinical mastitis	No effect	Inadequate
Sandoval (1998)	Chickens from 8 days old (N=800)	Baptisia tinctoria 30c vs. Antibiotics (ciprofloxacin) 10 days	Q. exp.	Salmonella infection	Effect same as effect with antibiotic	Inadequate
Albrecht (1999)	Piglets (N=1440)	Homeopathic metaphylaxis vs. placebo, low dose antibiotic metaphylaxis, and therapeutic dose antibiotic metaphylaxis 11 days	Q. exp.	General disorders Bronchial disorders	Sign. difference compared with placebo and low dose antibiotic metaphylaxis.	Inadequate (no blinding)
Anderson (1996, 1997, 1999)	Dairy cows with increased SCC in milk (N=48)	Intracysternal administration of Lachesis D8 / Placebo / no treatment	Q. exp.	LDH activity Cell count	No effect	Inadequate
Elliott (2001)	Horse / dogs with Cushing's disease (N=41)	Quercus Robur 30c and ACTH	Coh.	clinical symptoms	80% improvement	Inadequate

3.1.3. Conclusion

Based on the results of four reviews and an analysis of sixteen previously unreviewed trials chosen at random into the effect of homeopathic treatments in human and veterinary medicine, we must conclude that the

empirical evidence of a link between homeopathic treatment and subsequent effect is (still) weak. Nonetheless a conclusion common to all the reviews was that there is some evidence that homeopathy is effective. All the reviews also refer to the problems of possible publication bias and the generally poor methodological quality of the trials. We thus agree with the final conclusion of the authors of the reviews who suggest that there is a valid case for further evaluation of homeopathy, but that it should be based on trials of good methodological quality.

3.2. Obstacle to core research: evidence for the similia law

The similia principle (see Chapter 4) does not apply exclusively to homeopathy, it is a law which has traditionally been applied in very many contexts, for example in vaccines. Recent developments in the field of vaccines show that these are no longer only used in advance to activate the immune system, but also after the fact (following an infection) where there is insufficient natural immune response. Important research into the validity of the similia principle (homeopathy and isopathy) was carried out by a group of cellular biologists at Utrecht University (Van Wijk and Wiegant, 1989, 1994a, 1994b, 1997; Van Wijk, 1992; Wiegant, Van Rijn and Van Wijk, 1997). They demonstrated that *'if low doses of harmful conditions are administered according to similia principle there is a stimulation at cellular level of the capacity for survival (expressed in terms of development of tolerance) and a stimulation of 'protector proteins.'* (Kramers, 1998). The crux of the Utrecht research is that after prior (proteotoxic) damage to the cell (via a 'heat shock' with sodium arsenite or cadmium) a form of self-recovery is stimulated which is characterised by a transient phase during which the cell is extra sensitive to the original stressor. In this period of extra sensitivity self-recovery (survival capacity) can be further stimulated by administration of the relevant stressor in a smaller dose than the dose which caused the damage. In this context we refer to a transitory sensitivity system. In cells, disrupted self-recovery is stimulated by extra production of certain protector proteins which are normally present in the cell (HSPs, heat shock proteins). Proteotoxically damaged cells which *do not* receive the follow-up treatment with a low dose show a lesser synthesis of the protective proteins and a poorer survival capacity.

Further research showed that the quantity of protective proteins and the survival capacity of the cells also increased after administration of a low dose of another (heterologous) stressor, other than the original proteotoxic stressor: for example 'heat shock' followed by cadmium. The more the reaction patterns ('remedy pictures') which can cause both stressors in the cells resembled each other (similia law), the greater the increase proved to be. This finding strongly supports the validity of the similia principle. *'The similia principle (in the high dilutions to be discussed separately below) is often linked with the 'Arndt-Schultz law'. This law states that biological systems react differently to different doses of toxic substances. Pharmacologist Hugo Schulz observed in his experiments with yeast cells, for example, that chemical compounds which retard the growth and respiration of yeast, actually have a stimulating effect in much lower doses. Later the name 'hormesis' was attached to this law – which was mooted long before Hahnemann, in Hippocrates, Paracelsus and Hufeland. Over the last forty years there has been ever increasing scientific evidence for the conclusion that biological, physiological or biochemical reactions to a drug in a low dose can be completely opposite to reactions to a larger dose. The hormesis concept is however also fiercely disputed: in modern pharmacology dose-dependent reversal effects are explained in terms of selective antagonistic mechanisms according to the current receptor model (Forth, 1985).'* Kramers (1998)

3.3. Obstacle to core research: efficacy of high dilutions⁴

In 1954 research was carried out into starch-splitting with the enzyme diastase. From this (single blind) trial it transpired that high doses of mercury retarded this splitting, while potentised mercury (D61) accelerated it (Boyd, 1954; Pelikan and Unger, 1971). Botanical trials conducted in the nineteen twenties are even more classic: increasing potencies (up to D60) of certain substances (e.g. iron sulphate and gold chloride) in the medium resulted, in a reproducible manner, in sinus-shaped germination and growth curves in wheat. Comparable growth curves were found in the twenties in cultures of paramecia (Junker, 1925, 1928). Amons

⁴ Most of the text is drawn from: Kramers (1998)

and Van Mansvelt (1972) determined similar growth retardation in lymphoblastic mouse cells (see also Van Mansvelt and Amons, 1975).

More recent work has been carried out by French immunologist Benveniste (Poitevin *et al.*, 1988) of the INSERM Institute in Paris. Publication of their research results in *Nature* gave rise to a world-wide debate. The research group demonstrated that human basophil granulocytes show *degranulation* (achromasia), even with administration of extremely dilute concentrations of anti-IgE antiserum. It was also demonstrated that heating and radiation of the antiserum counteracted this effect. Benveniste also showed that potentised bee poison (*Apis* C15, C16, C17 and C20) retards the degranulation of basophils despite the addition of anti-IgE in normal doses. The experiment was in the first instance replicated by Maddox *et al.* (1988) without reproducing the result. However, in 1999 four independent research institutes in France, Belgium, Italy and the Netherlands (Belon and Crumps, 1999) replicated the research and confirmed Benveniste's findings. (Bio)chemical studies show that potencies and normal dilutions vary in their impact on the activity of certain enzymes. Physicists are researching into the characteristics of high dilutions using NMR spectra among other things. Decades ago Smith and Boericke (1968) had already demonstrated changes in the Nuclear Magnetic Resonance (NMR) spectrum of extreme dilutions. More recent NMR studies have reached similar conclusions (Demangeat *et al.*, 1992; Weingärtner, 1992).

To summarise we can state that there is some empirical evidence for the efficacy of homeopathic treatments. Both the outcome trial of homeopathic treatments in man and animals, and the fundamental empirical research into the validity of the similia principle and the efficacy of high dilutions produce results which tend to corroborate this.

3.4. Practice development research

Practice development research aims to improve the quality and thus also the professionalism of homeopathic practice (professional practice). The practice of homeopathic treatment is a logical progression from the underlying theoretical model. On this basis homeopathy can be characterised as one of the holistic forms of complementary health care (Aakster, 2001). From this standpoint we will describe in the following section the obstacles to homeopathic treatment in organic farming practice.

To fully understand the problems it is important to grasp the distinction in the concept of sickness and health between conventional and homeopathic medicine, and the associated methods of treatment and choice of therapy (see 4.4.1).

3.4.1. The method of choosing a therapy

Within the framework of the development of Evidence Based Medicine, the choice of therapy in conventional medicine is increasingly based on the results of treatments which have been tested for effectiveness (ideally in randomised double blind clinical trials). The aim of this approach is to arrive as far as possible at treatments laid down in protocols for clearly defined disease-specific indications.

Complementary forms of medicine, by contrast, are characterised by often individually tailored diagnoses with appropriate personalised treatment, complex interventions, with emphasis on maximising the capacity for self-healing, and treatment of the entire organism (Aakster, 2001). This also applies in part to homeopathy. At a fundamental level remedies are chosen for specific clusters of symptoms. At a slightly higher level remedies are chosen which correspond to specific patient typologies. Finally there is another level at which the choice of medication depends on the one hand on the unique individual situation and on the other hand on the stage and nature of the stage in the therapeutic process. *'The homeopathic doctor is thus looking for the most significant characteristics of this patient. Particular traits which only a few people share become significant because these are the most characteristic. Some pieces of information are thus more important than others. The homeopathic doctor ranks sometimes dozens of pieces of information which a single patient can provide. When all the information is collected and placed in order of precedence the doctor seeks out exactly that remedy which best suits this patient from more than a thousand homeopathic remedies.'* (Rutten, 2002).

Many practitioners of complementary forms of medicine thus also indicate that they distinguish between knowledge obtained experimentally and that based on experience. Experience manifests itself in three different ways:

- historical knowledge / insights and ideas / methods passed down by earlier practitioners (often to be found in specialist literature),
- reflection during the practitioner's career on the knowledge accrued and his/her own experience with health, sickness, treatment, etc., and
- information which comes to light during the process of treating the individual patient (Aakster, 2001).

The question is however whether this form of therapy selection has any scientific legitimacy. The short and clear answer is yes! There are sufficient points of departure in the scientific literature to legitimise the use of experiential knowledge in addition to the protocol-based approach. For example Kaasenbrood, in his thesis '*Consensus als criterium*' (Consensus as criterion, 1995) on the use of protocols and guidelines in conventional psychiatric practice, advises basing the development of guidelines for psychiatric treatments on both the results of empirical research and the experiential knowledge of experts. Experienced workers, experts, have learned more or less consciously to deal with the prevailing laws and situations in their field (expertise, tacit knowledge, clinical eye, craftsmanship or professional skill, green fingers, etc). In many cases this experience produces valid knowledge (Kuhn, 1977; De Groot, 1978; Snoek, 1993; Glas, 1997). This knowledge of experts (expertise) is represented on an intermediate level of abstraction, called 'moderately abstract conceptual representation' (MACR). This level is a compromise between abstractions, such as comparisons in physics or chemistry, and concrete specific problems (Zeitz, 1997). This knowledge enables them to recognise 'prototypical situations' based on pattern recognition (Glas, 1997), to see the present problems in this light and by having an overview of the situation and laws, to perform adequately and in accordance with the situation (Snoek, 1993; Brouwer, 1994). Adequate knowledge of the prevailing laws of their sphere of work and how to apply them in different situations provides the opportunity for self-regulation, the '*adaptive use of skill across changing personal and environmental conditions*' (Boekaerts *et al.*, 2000). In this context self-regulation is dependent on the trained judgement of the individual person. Reflection on and explicit expression of this knowledge offer the opportunity to achieve ideal knowledge and develop vision (Baars and De Vries, 1999). Finally, conscious use of unique patterns offers the opportunity to make causal relationships in individual cases. This is done by establishing the correspondence in unique pattern (Kiene, 1998; Baars, 1997; Baars, 2000; Swanborn, 2000) between intervention and subsequent effect (see also proposal for solutions to Obstacle 5, in section 6.5)

3.5. Obstacles to practice development research

One of the prime problems is that current developments in Evidence Based Medicine threaten to impose on homeopathic practice firmly defined research and treatment protocols for specific indications. However, based on its theoretical background homeopathic practice is fundamentally different from conventional practice and can only be subjected to protocols up to a certain level. The area which cannot be put into protocols, the selection of medications, is based on the one hand on typological pattern recognition ('which remedies suit which types of patients?') and on the other hand on being able to assess individual aspects of the patient, their context and the stage of the therapeutic process (Baars, in prep.). In short, this area is as yet based partly on the trained judgement of the doctor or therapist. Making up protocols as a way of improving quality in professional performance is only worthwhile at the most basic level of selection of therapy, where the selection of the therapy is directly linked to the cluster of symptoms. If it were also to be applied to other levels this would be to the detriment of the individual nature of homeopathic treatment and would thus reduce the quality of treatment instead of improving it.

A second problem relates to evaluating the effect of homeopathic treatments. In conventional medicine this is done wherever possible with the aid of experimental research based on treatment protocols. As already mentioned above, a part of the process of (continuous, i.e. successive) selection of medication cannot be put into a protocol, rather it is based on the judgement of the trained practitioner. Thus with regard to the evaluation of the outcome of treatment with a view to improving the quality of treatment practice, it can be said that the current research methods are inadequate for use in the practice of homeopathic treatment.

3.6. Obstacles to supporting research in homeopathy

In a series of articles, 'Dwalingen in de methodologie', in the Dutch Medical Journal, *Nederlands Tijdschrift voor Geneeskunde* (NTGV) of 20 April 2002, Rosendaal and Bouter maintained that research into homeopathy was completely pointless. Their argument is that the *'prior expectation concerning a hypothesis determines whether research is worthwhile. Our prior expectation in relation to homeopathy is nil, and so research is pointless to us.'* ... *'Although there can be differences in prior possibility between experts, not all views are of equal weight: it must be possible to support a prior possibility with reasonable arguments.* The position of Bouter and Rosendaal is that: *the fundamentals of chemistry, biology and pharmacology are opposed to the efficacy of practically infinitely diluted solutions.'*

This quote is a perfect illustration of *the* theoretical obstacle to scientific (and frequently associated social) acceptance of the therapeutic use of dilute and potentised solutions of substances, as used in homeopathy. Many people, including the authors quoted above, maintain that homeopathy cannot be effective because it does not conform to the recognised scientific - in this case biological, chemical and pharmacological - theories and perceptions. Even if repeated optimum outcome studies of the effect of a homeopathic treatment led in theory to repeated determination of an association, one cannot and may not conclude that homeopathy is effective, because it simple *cannot* be effective. The 'reasonable argument' here is that very dilute solutions (diluted beyond Avogadro's number) can have no effect because of the absence of material particles which could bring about the effect. The alternative explanation often offered for any effect produced is the presence of the placebo effect.

This reasoning can easily be recognised as an application of one of the basic arguments, namely that of 'compatibility with the state of the science', which is used in scientific arguments for or against the causal nature of an observed association (Hill, 1965; Campbell and Stanley, 1966; Cook and Campbell, 1979; Rothman and Greenland, 1998; Kluiters and Ormel, 1999). There are two aspects to this argument. It must be possible to make the association based on recognised, in this case biological, theories and perceptions. Secondly the association must not conflict with accepted biological facts and laws. If the association does not meet these criteria, one should not jump to the conclusion of causality too rashly. It is clear that this 'causality argument' is being raised in the argument of Rosendaal and Bouter above. However the two authors omit to mention the last part of the compatibility argument, namely: *'On the other hand, these criteria certainly need not be interpreted in absolute terms. Findings which do not meet the criteria may after all point to new insights which may refute or supersede previous ones.'* (Kluiters and Ormel, 1999).

3.6.1. Obstacle to supporting research: causality arguments

If homeopathy is to gain scientific acceptance causality arguments will have to be raised. These arguments are partly methodological and statistical in nature and partly substantive and/or formal-logical (Kluiters en Ormel, 1999). The methodological-statistical arguments must be used in the evaluation of empirical trials on the effect of homeopathic treatments as well as in empirical studies on the validity of the similia law and the efficacy of high dilutions in fundamental research. These have already been discussed in section 4.2. The substantive and/or formal-logical arguments must relate to the tenability of the theory that homeopathy can be therapeutically effective in terms of compatibility with the state of the science.

Given the fact that the overview of the empirical studies into the effect of homeopathic treatments gives a first indication that homeopathy could be effective, it is worthwhile to consider the compatibility of the theoretical concept of homeopathy with the current state of the science. The argumentation used here must be logically constructed from three parts:

- convincing arguments that 'ontological reductionism' (the theory that effects in nature can only be traced back to material particles) has shortcomings as a theoretical framework,
- convincing arguments that homeopathic dilutions can bring about a therapeutic effect, and
- convincing arguments that the effect of a homeopathic treatment cannot be reduced to a placebo effect.

3.6.2. Obstacle to supporting research: ontological reductionism

To make a convincing argument that ontological reductionism has shortcomings as a theoretical framework we turn first to the philosophical framework of Oost (1999). In his thesis '*De kwaliteit van probleemstellingen*' (the quality of the formulation of questions) Oost states that existing theories may fail:

- on internal conceptual grounds: a theory is logically inconsistent or works with circular or ambiguous concepts,
- on external conceptual grounds: a theory 'clashes' with other theories, and/or
- on empirical grounds: a theory 'clashes' with reality.

After a brief introduction to the problems of reductionism and holism we will discuss arguments at the three levels referred to above.

Reductionism and holism or organicism

In scientific theory reductionism is usually set against holism or organicism. The statement: '*An organism is essentially nothing but a complex set of atoms and molecules*' lies at the heart of reductionism. The statements '*You cannot just simply reduce an organism to a sack of molecules*' and '*the whole is greater than the sum of the parts*' essentially characterise holism. The reductionist model argues that all traits and other characteristics of living organisms, their morphology, physiology, behaviour and ecology, can ultimately be fully and exclusively explained in terms of the physical and chemical molecules (DNA, proteins, etc.) of which they are composed. Reductionism assumes that the laws, concepts and theories formulated for a higher level of organisation in biology (for example the level of the organism) can be explained by theories developed for a lower level of organisation, such as the level of organs, tissue and cells. This means that ultimately all biological concepts, laws and theories can be reduced to the physical and chemical.

Looijen (1998) points out in his philosophical thesis '*Holism and reductionism in biology and ecology*' that three aspects must be distinguished in the reductionism-holism problem: the ontological, epistemological and methodological aspects.

Ontological aspects relate to the question of which entities, things or substances are assumed to make up reality (nature), which characteristics are attributed to these things or entities and what relationships and functions can be assumed to exist between them. *Epistemological* aspects relate to our knowledge of reality, the way in which this knowledge is expressed in (among other things) theories, and to logical connections between theories. In particular they relate to links between theories developed for different areas of reality or for different levels of organisation. *Methodological* aspects relate to the way in which knowledge is obtained and the basic principles, laws and strategies used in doing so. In particular this is concerned with the question of whether, to arrive at the 'correct' knowledge or understanding of a certain level of organisation (the level of the whole), we should study the underlying lower levels or organisations (the component parts and their interactions) or the higher level itself, or perhaps its relationship to still higher levels.

Reductionist and organicist or holistic descriptions and theories have alternated in science since the Middle Ages. Verhoog (1993) summarises this trend as follows: 'In the medieval notion of reading the Book of Nature, nature is seen as an organism, as the body of Mother Earth, a harmonious and self-regulating entity which is treated with respect. In the sixteenth century this concept of nature was replaced by the concept of 'fallen nature'. Nature is now seen as disorderly and chaotic; the 'blind' forces of nature must be controlled by human reason. Thus man is no longer seen as an intrinsic element in a nature created by God. Nature is objectivised and materialised during the scientific revolution in the sixteenth and seventeenth centuries. In a nature no longer guided by divine providence, man is free to manipulate and use nature as an instrument. Experimental science provided the means to do this. Professor of Philosophy Gloy (1996), in her book '*Das Verständnis der Natur – II. Die Geschichte des ganzheitlichen Denkens*' describes the historical development of organicist thought as a development in stages: current ecological thinking was preceded by natural magic in the Renaissance (end 14th – end 16th century), Leibniz' Monadology, the natural philosophy of German Idealism and the Romantic Movement, and vitalistic and holistic concepts at the start of the 20th century. It is evident that reductionism often predominates in current social and scientific thinking.

The failure of reductionism on internal conceptual grounds

As already mentioned, ontological reductionism is based on the idea that all traits and other characteristics of living organisms can ultimately be fully and exclusively explained in terms of the physical and chemical molecules (DNA, proteins, etc.) of which they are composed. And this even applies to human thinking! However, in any attempt to explain how reality is constructed one must begin by formulating thoughts about the phenomena in the world. Ontological reductionism thus begins with thoughts about matter. Consequently it is immediately faced with two different areas: the material world and thinking about the material world. It tries to understand the latter by construing it as a purely material process. It assumes that thinking in the brain comes about in roughly the same way as digestion in the metabolic organs. As ontological reductionism attributes mechanical and organic operations to matter, so it also ascribes to matter the capacity, under certain circumstances, to think. It forgets, however, that it has now merely shifted the problem. Ontological reductionism ascribes the capacity for thought to matter, instead of to the person himself. This brings it back to where it started. How does matter manage to think about its own being? Why is it not simply content with itself and accept its existence? The ontological reductionistic view is not capable of solving this problem: it can only shift it (Steiner, 1998; Baars, 1995).

The failure of reductionism on external conceptual grounds

In the meantime there are various modern theories which 'clash' with the theory of ontological reductionism. For example, modern chaos theory, which seeks to explain biological systems, takes into account those very processes which in reductionist terms are no longer linked by a linear-causal relationship (Reiber, 1994). According to the researchers the reason for this is that these linear-causal arguments are inadequate to explain the complexity of biological system.

Nobel prize-winning neuro-physiologist Eccles (1994), based on his research into the human brain, indicates that reductionist science cannot explain our spiritual existence. He comes to the conclusion that mental events can trigger neuronal effects.

Linear-causal explanations also fail in terms of theories in the field of physiological and psychological self-regulation of living organisms⁵. Researchers come to the conclusion that life is a process in which there is no question of standstill, since everything is in a state of continuous development (and decay). A living organism is autopoietic, a self-creating dynamic reality, and must therefore be fundamentally distinct from machines, which can never make, repair, reproduce or activate themselves. An organism is an entity in which the organs function in harmonic, efficient mutual cooperation. Each part of an organism can only understand the organs in terms of the functional relationship with the other parts. (Penzlin, 1994; Maturana, 1982). Rist (2001) based on a review of the literature on the various concepts of physiological self-regulation says that the various theories indicate that biological life can no longer be conceived of as linear-causal, because living beings must be regarded as autonomous units distinct from the environment. Central to the various physiological self-regulation theories is the concept of species as 'cause' of the state in which the system repeatedly finds itself, irrespective of its starting position. Thus the researchers maintain that it is also the species that 'uses' the genes as an instrument, and not the other way round.

If we look at theories in the field of psychological self-regulation we find similar conclusions. Through self-regulation experts are in a position to make 'adaptive use of skill across changing personal and environmental conditions' (Boekaerts *et al.*, 2000). The guiding principle is knowledge of the laws and the knowledge and skills to use this knowledge adequately 'across changing personal and environmental conditions'. Baars (2000) defines self-regulation as 'a system in which on the one hand there is a *general* autonomous coherent pattern of observations, decisions and actions, which on the other hand is capable of taking on *specific* forms, depending on what is observed. A general 'Fließgestalt' (literally: flowing, mobile shape or form) thus, from which to interpret the various aspects of a specific situation. This pattern has its origin in (experiential) knowledge and consists of *knowing what* in combination with *knowing how*. This system is in essence aimed at and is capable of autonomous choice of action which is adequate for the

⁵ The biologist Stephen Rose (1997) writes: '*Reductive methodology has served the simpler sciences of physics and chemistry well for three hundred years, and it is still the method of choice for most of the experimental work biologists do. But it may be failing us in our attempts to solve the more complex problems presented by the living world with which the biological sciences must now wrestle.*' '*The organism is both the weaver and the pattern it weaves, the choreographer and the dance that is danced.*'.

situation. Self-regulation can take place at the *psychological* level (autonomy) and at *biological* level (in medicine referred to as *hygiogenesis*).⁶

Research into biorhythms / chronobiology is directly connected to this⁶.

In conclusion we may say that none of these theories start from the premise of a linear-causal explanation in which the whole is made up of the parts, instead we conclude that there must be a Gestalt, a dynamic pattern or 'entirety of knowledge' which is the cause of the form and function of organs and organisms, and of action adequate to the situation. In addition, not a single geneticist, based on his knowledge of material which can be understood in biochemical and biophysical terms, can trace the form or function of even a single organ of any organism back to a model (Kiene, 1994). Holistic researchers on the other hand have been able to do so and have developed new scientific research methods for this purpose (Schad, 1971; Bockemühl, 1982; Göbel, 1988; Bortoft, 1996; Kiene, 1998; Baars and De Vries, 1999; Kiene, 2001; Baars, 2001). Researchers have also been able to describe and explain physiological and embryological processes, among others, based on this 'Gestalt approach' (Van der Bie, 2001; Van Telling, 2001).

The failure of reductionism on empirical grounds

The behavioural properties of parts of an organism often cannot simply be explained in terms of their function within the whole. Functional explanations are inescapable in biology. And because they do not occur in physics and chemistry, they form an important argument for a positive distinction between biology and these other sciences (Looijen, 1998).

Professor and zoologist Stephen Jay Gould (2001) made the surprising statement that an organism must be explained as a whole organism and not as a sum of genes. According to Gould the disappointment of the discovery during the charting of the human gene map that a human has only one and a half times as many genes as an earthworm also has an up side, namely that the reductionistic way of thinking is no longer tenable for living, complex organisms. Later declarations that there must be networks of gene functions do not offer a solution to this conceptual problem, they only shift it. After all, how can these networks themselves be explained from the working of DNA

The embryologist Van der Wal (Van der Wal and Lammerts van Bueren, 1993) observed that DNA 'was driven by the environment' and not the other way round: *'Developmental biology - including embryology - is dubbed the instructor for insight into the phenomenon of development. A consideration of the process of differentiation in the embryo alone makes it impossible to go on regarding DNA, cells, etc., as the primary attributes of a living organism. The biological nature of cells, tissue, 'parts' is (in part) determined by the nature of the environment (e.g. metabolic conditions, spatial position in the whole) and can change over time. The genome (this is the entirety of genetic coding laid down in the nucleus of cells) does not change, but during differentiation, in the context of the peripheral environment of the cell, is subject to external influences. It is established that differentiation is an 'outside-in' process, not the other way around. The DNA plays the role of 'constraint', this is the retention of potencies in the second instance; the periphery manipulates these potencies. The DNA 'is not expressed', its options are determined from 'outside in'. The definition of a gene as 'a piece of DNA' is not meaningful. What is a 'gene' without the context of the organism within which it is manifest? The DNA molecule is no more nor less than the centre in an ecological context which can be called the 'genotype' or 'cell' or 'organism.'*

It emerges increasingly clear in neuro-physiological research (Meijer 2002) into the biological clock of the rat that there is a considerable difference between the clock in the intact animal and the isolated structure.

⁶ For example Roßlenbroich (1994) defines a rhythm as *'Ein kontinuierliche Bewegung zwischen polaren Gegensätzen, die sich in ähnliche Zeitverhältnissen regelmässig wiederholt. Das Durchlaufen der Gegensätze ergibt Betonungen, ihre Verbindung durch die Bewegung im Ablaufenden Prozess führt zu Geschlossenheit und Ganzheit des Ablaufs.'... 'Durch die Bewegung, das heisst durch den ablaufenden Prozess, erfahren die Extremen eine Verbindung. Diese Verbindung ist also nur durch den Prozess vorhanden. Aber auch die Extreme existieren nur durch den Prozess. Weil es in der bewegten See einen Wellenberg gibt, gibt es ein Wellental; nur weil es die Dunkelheit der Nacht gibt, erscheint der Tag als hell, sonst würde er als Dauerzustand keine besondere Qualität haben. So kann Rythmus auch nicht aus einzelnen Elementen betsimmt werden, sondern nur aus dem Ganzen des Prozesses.'... 'Kehren wir wider zurück zur Biologie. Wir haben gesehen dat Organismen offensichtlich vielfaltig und komplex schwingende Systeme sind. Leben kann niemals als ein Zustand, sondern nur als eine dynamische, zeitliche Ordnung verstanden werden. Diese Ordnung besteht im prozesshaften Wechsel zwischen verschiedenen Funktionsrichtungen, die jeweils im Rythmus ausgeglichen werden. Jeder Bewegung folgt eine Gegenbewegung, die die Geschlossenheit des Vorganges herstellt. Entgleist dieser Wechsel, entstehen Krankheit oder Zusammenbruch der Lebensvorgänge.'*

Meijer sees it as a clear example of emergence: *'You see patterns appearing in the gene network which work in a somewhat more complex manner at the protein level. At the level of neuronal networks new properties come into being which were not present at the genetic level. Finally brain structures and the rest of the body also start up an interaction which again delivers a new outcome.'*

The presence of emergent properties in self-organising systems is also described by Camazine *et al.* (2001) in their book 'Self-organization in biological systems': *'Emergence refers to a process by which a system of interacting subunits acquires qualitatively new properties that cannot be understood as the simple addition of their individual contributions. Since these system-level properties arise unexpectedly from non-linear interactions among a system's component, the term emergent property may suggest to some a mysterious property that materializes magically.'*⁷

Empirical phenomena perfectly demonstrate that ontological reductionism is not tenable on empirical grounds. As shown by these examples, not all properties and other characteristics of living organisms can ultimately be fully and exclusively explained in terms of the physical and chemical molecules (DNA, proteins, etc.) of which they are composed.

Now that we have demonstrated that ontological reductionism fails as a theoretical framework on both internal and external conceptual grounds, and on empirical grounds, we turn our attention to arguments to demonstrate that homeopathic dilutions can activate a therapeutic effect and that the impact of a homeopathic treatment cannot be attributed to a placebo effect.

3.6.3. Obstacles to supporting research: arguments concerning therapeutic effect

Van Wijk and Wiegant (1997) examined the validity of the *similia principle*. With their research they showed that 'if low doses of harmful conditions are administered according to the similia principle the capacity for survival (expressed in terms of development of tolerance) is stimulated at cellular level and protector proteins are also stimulated.' The research gives an important indication of a regulatory mechanism on which the similia principle is founded. Eskinazi (1999) expounded on the scientific state of affairs with regard to the theoretical objections to homeopathy. With modern insights there is little left of the theoretical objections. First the objection to the theory that pathogenic substances can also cure. The author gives an extensive list of examples in which this principle also applies in conventional medicine. This principle has also now been recognised in cellular biology and is known as hormesis. The most surprising thing is that it was a conventional scientist who removed the objection to high dilutions.

3.6.4. Obstacles to supporting research: placebo-effect

Recent articles by two research groups have raised doubts about the scale and even about the existence of the placebo effect. Kienle (1995) carried out a critical analysis of Beecher's fundamental research which produced the initial concept of the 'Powerful Placebo'. She describes a multitude of weaknesses in these studies and demonstrates that all Beecher's so-called proofs of the placebo effect could have other explanations. From an entirely different point of view, Danish researchers Hrobjartsson and Gotzsche (2001) reviewed 130 clinical trials in which a placebo was compared with an experimental treatment. They

⁷ The following example described by Camazine *et al.* (2001) demonstrates the principle of emergence: *'The eggs of Dendroctonus beetles are laid in batches beneath the bark of spruce trees. Larvae hatch from the eggs and feed as a group, side by side, on the phloem tissues just inside the tree bark. Previous studies have shown that the larvae emit an attractive pheromone. In a series of experiments the larvae were randomly placed on a circular sheet of filter paper 24 cm in diameter between two glass plates separated by 3 mm to allow the larvae free movement. The subsequent positions of the larvae were observed over time. The degree of clustering exhibited by the larvae was found to depend strongly on the initial larval density. At low density (0.04 larvae/cm²), a loose cluster appeared, but it did so only slowly, in approximately 1 hour, and comprised only 25 percent of the population. In contrast, at high density (0.17 larvae/cm²) a single tight cluster rapidly assembled. Within 5 minutes about 50% of the larvae were clustered in the arena's center and after 20 minutes some 90 percent of the larvae joined this cluster. The experiments demonstrated a simple emergent property – a cluster- in a group where the individuals initially were homogeneously distributed. At a certain density of larvae, the system spontaneously organizes itself.'*

concluded on this basis that it was unlikely that the so-called placebo effect could lead to significant changes in the parameters of physical diseases, but that it can lead to significant changes in psychological disturbances, such as anxiety. Given the notion that a placebo is in essence a psychological phenomenon (for example, the thought and feeling that you are receiving something which will probably help), the researchers' conclusion that placebos only have a significant psychological and not a physical effect, is understandable.

3.7. Conclusion, supporting research: failure of ontological reductionism

Based on the arguments raised above, it is clear that the theory of ontological reductionism fails on internal and external conceptual grounds, as well as empirical grounds. It is also demonstrated that there is evidence of a working mechanism underlying the similia law. Finally it is clear that the alternative explanation – i.e. the placebo effect – for a subsequent effect in studies on the effect of a homeopathic treatment, is unlikely. This disposes of *the* theoretical obstacle to the acceptance of homeopathy, namely that a homeopathic treatment cannot be effective because the working mechanism is not compatible with recognised scientific, in this case, biological, chemical and pharmacological, theories and insights.

Furthermore there is the discovery that many scientific facts argue in favour of the theory of ontological holism. This raises the question of why it is not more widely embraced as a theory in science. In our view this is due to the deep-seated belief that effects in nature can only be attributed to material phenomena. Many people are unaware that this belief was not held throughout the majority of human history. From Plato (427 - 347 BC) and Aristotle (384 - 322 BC) to the middle ages however the notion has existed in scientific history that there is a world of ideas which, as causal principles, give shape to things in nature. These ideas or universals were seen as complex, differentiated systems of forces which gave an organism such as a plant or a human being its shape and enabled it to keep it. Both Plato and Aristotle maintained that such causal principles existed, and that they could be known and understood: according to Plato, by looking in thought into a spiritual world of ideas and according to Aristotle by turning one's sights on the world of the individual things (Hartmann, 1941; Kiene, 1998). In the medieval debate on universals, this world of ideas was not denied, but Realists and Nominalists argued about whether these causal principles could be known to man. The debate was eventually won by the Nominalists and the question was answered in the negative. The next historical milestone was the work of Francis Bacon in the 17th century. Bacon argued in his 'Novum Organon' that the task of the scientist should not be the broad sweep of ideas, but careful observation and experimentation. A final phase in this historical development came in the second half of the 19th century and the start of the 20th century. In this period, following on from the previous historical views that man could not know the causal principles of forms (universals debate) and that it was not the task of the scientist to know these principles (Bacon), the existence of this body of causal principles was denied. Rudolf Virchow (1907) summarised the biological and medical view of his time as follows: *'Modern medicine has defined its view as mechanical, its aim as establishing a physics of organisms. This has shown that life is merely an expression of a sum of phenomena each of which proceeds separately according to the normal physical and chemical (that is to say mechanical) laws. It denies the existence of an independent life force and natural curative power.'* (Source: Kiene, 1994)⁸.

This summary conclusion illustrates the historical steps which led to the gradual denial of the existence of causal principles and the reduction of the cause of natural phenomena to the functioning of material particles. Causal-mechanistic or ontological reductionist thinking is an expression of this development. We have demonstrated above that this theory is not tenable on a number of grounds. To arrive at a reasonable alternative we have to look more closely at the question of causality.

If an experienced tennis player hits a perfect shot at Wimbledon there is, at the physiological level, a sequence of biochemical reactions in time. In this case there must be a transfer of information which causes all the biochemical steps in time to be attuned to each other so that ultimately the entire process of

⁸ See also Emil du Bois-Reymond (1918) who wrote: *Brücke and I pledged a solemn oath to put in power this truth: No other forces than the common physical-chemical ones are active within the organism*

Hermann von Helmholtz wrote in similar terms: *'Natural phenomena must be reduced to the movement of matter with unchanging motive forces, which depend solely on spatial relationships. ... The task of physical science therefore ultimately confines itself to reducing natural phenomena to constant attractive and repellent forces, the intensity of which depends on the distance. The solution to this problem is at the same time the precondition for a complete understanding of nature.'*

preparation and execution lead to the ball hitting exactly the right place at exactly the right time. We could call this a 'time Gestalt'. In a general sense all this applies afresh to a subsequent but different perfect shot in another place. However, since this is another type of shot there is a different 'time Gestalt'. In this 'Gestalt' we can distinguish two causal layers: a vertical and a horizontal layer. In the horizontal layer there seems at first sight to be a cause-effect chain because, for example, increasing the hormone level leads to an increase in the glucose level in the blood. Each preceding 'cause' in time leads to a subsequent 'effect' in time. However, on further consideration there is a problem here which was previously identified by Bertrand Russell. That is that an effect which precedes something in time, no longer exists when the effect occurs. The cause has already disappeared. How can a cause which no longer exists bring about an effect? (Kiene, unpublished). To solve this problem the scientific literature turns to the concept of 'information'. The information is supposedly transferred from one stage to the following stage. This brings us to the second, vertical, layer of causality. In the case of the perfect shot, but also in other self-regulatory skills, and the self-organising physiological processes which can only be understood in terms of the species, there is a hierarchically higher-ranked principle that provides the coherence between, say, biochemical stages in time, but which also provides the context for the object of all the processes as a whole, namely performing this specific tennis shot at this moment or creating this specific tissue structure. The principle also provides an explanation for the transfer of information between the various stages in time in the horizontal causality layer. This higher-ranked principle is not immediately perceptible to the senses, but is manifest in bringing coherence in time and space.

Homeopathy, and also anthroposophic medicine, assumes this sort of higher-ranked and forming principle in nature. The pharmaceutical processes used in these forms of complementary medicine, are aimed at releasing these forming or in-*form*-ing principles from matter which is set in time and space. In this way these matterless forming forces can be used as medication. From this point of view it is also conceivable that there are medications in which no material molecules remain.

4. Obstacles to veterinary homeopathy: practical and legal

Liesbeth Ellinger

There are currently some 2,550 practising veterinary practitioners in the Netherlands (Source: K.N.M.V.D.). Of these around 800 prescribe homeopathic remedies, and then specifically the 'complex remedies' which are easier to prescribe. Around 170 vets prescribe single homeopathic remedies, which requires a greater knowledge of homeopathy. Most veterinary practitioners are concerned with the treatment of small pets and horses. Only around 35 vets treat farm animals with homeopathy⁹. Lack of background information, fed by doubt about whether or how homeopathic remedies work, means that vets regularly opt for conventional rather than homeopathic treatment.

Homeopathy is thus not widely used for farm animals. Because homeopathy requires a more individual approach to the sick animal it can also be more difficult to administer standard remedies in the event of sickness or disease. Experience in selecting and working with homeopathic remedies is important for the successful treatment of animals. Most veterinary practitioners and livestock farmers lack this experience. There is no recognised training course for veterinary homeopaths. The Veterinary Medicine Faculty only offers a two-week course on homeopathy, phytotherapy and acupuncture as a third-year option. In the new curriculum these subjects will be accommodated in the basic timetable. In degree courses in medicine the only provision is a special Chair of Homeopathy at the University of Amsterdam, where students can take optional subjects. At Wageningen University the homeopathic veterinary medicine course is incorporated into the course for homeopathic doctors. Part of the course is taught by vets, while the majority is taught by homeopathic doctors.

The knowledge and skill of a conventional veterinary practitioner are not really attuned to the wishes and lines of enquiry of organic livestock farmers (Vaarst *et al.*, in prep.). In addition to individual, organic prevention strategies based on complex management there is a need for further insight into the options of phytotherapy and homeopathy within the concept of self-regulation of animals and systems.

Currently around 150 livestock farmers have completed a course in the use of homeopathic remedies on their own farm. They themselves use mostly single homeopathic remedies when their livestock are ill. A small number of livestock farmers consult a homeopathic veterinary practitioner on what remedies can be used and they also sometimes consult a 'human' homeopath, when there are no homeopathic vets available. Dairy farmers in particular use these methods, and one farmer who keeps goats for milk and sheep and pigs uses homeopathic remedies. (Source: Louis Bolk Institute).

Current practice among 'conventional vets' is aimed on the one hand at prevention through vaccine programmes with anti-parasites etc., and on the other hand at the treatment of sick animals or groups of animals. Fees are based partly on the investment of time and knowledge and partly on income from drug sales. The latter is often a considerable proportion of the whole. In the case of homeopathy the farmer is charged almost exclusively for the (large) investment of time and knowledge, since homeopathic remedies are very inexpensive. Given the fact that vets derive part of their income from drug sales this requires a change of attitude to methods of payment on the part of both vet and farmer.

Registered homeopathic and phytotherapeutic products are permissible for use in animals, including those intended for consumption, even on Milk Quality Chain and **Integrated Quality Control** farms. A list of permitted homeopathic veterinary medicines was drawn up in 1993. At the moment all the homeopathic remedies on this list can be used for all species of animal without a withdrawal period (**Veterinary Medicines Registration Office**, 1993). Legislation on human homeopathic remedies is currently being tightened up, and it is possible that this will be extended to veterinary medicines. If this happens a number of remedies will no longer be available, partly because the raw materials for the remedies have to be

⁹ Source: *Puur natuur*, distributor of homeopathic remedies

renewed every two years, and this will mean that certain homeopathic remedies will no longer be made (source is from protected species). The raw materials must also be rendered virus and bacteria free, which is not compatible with the preparation protocol for certain homeopathic remedies according to **the German Homeopathic Pharmacopoeia (HAB)**.

If the current list of homeopathic remedies is maintained, there is no problem in the short term: there will then be time to test the effects and operation of homeopathic remedies on farm animals in practice. A simple registration procedure for any new remedies with a homeopathic or phytotherapeutic base could ensure that useful and practical remedies stay within reach even for farm animals

Based on experience in England, Hovi (2001) advises livestock farmers who want to start using homeopathy:

- always to listen to the advice of their own veterinary practitioner, even if he/she has no experience of homeopathy;
- to take a training course in the use of homeopathy, if possible from an 'independent' body, such as a cooperative producers group or a homeopathic veterinary practitioner, and
- to check that the dispensing advice given is correct and is in line with health and welfare rules

Veterinary practitioners whose clients start using homeopathic remedies must:

- if possible take basic training in homeopathy;
- not hesitate to advise the farmer on matters such as welfare, health and safety and the control of zoonoses, and
- encourage their clients to make contact with a homeopathic veterinary practitioner in addition to the usual farm vet, while ensuring that responsibility for decisions is clearly defined.

Further relevant points are:

- Veterinary students can take courses on the use of homeopathy during their studies. Now that it is possible to specialise in farm animals from the outset of the degree course, the homeopathic element can also be aimed exclusively at farm animals
- Livestock farmers can take courses in homeopathy, so that they are in a position to detect the right symptoms for the selection of a homeopathic remedy, and to treat simple complaints themselves. As long as there is a shortage of veterinary practitioners with a knowledge of homeopathy, this will certainly be essential. Note: this point ties in with Liesbeth Ellinger's experience in the Netherlands.

5. Solutions to obstacles

Erik Baars, Ton Baars, Liesbeth Ellinger

5.1. Doubts concerning efficacy

Obstacle 1: There is often doubt among farmers, veterinary practitioners and policy makers about the efficacy of homeopathic treatments.

Proposal for solutions 1:

Improvement in the provision of information to farmers, veterinary practitioners and policy makers concerning the fact that there is some empirical evidence for the efficacy of homeopathic treatments. The information must cover both outcome research into homeopathic treatments in humans and animals, and fundamental empirical research into the validity of the similia law and the efficacy of high dilutions. Promotion by the government of more methodologically sound outcome research into the efficacy of homeopathic treatments and fundamental research into the validity of the similia law and the efficacy of high dilutions. In this way more evidence can be collected and it will provide greater clarity about any presence or absence of efficacy.

5.2. Methodology for clinical trials

Obstacle 2: Research into the effects of homeopathic treatments is often characterised by a poor methodological approach and the risk of publication bias.

Proposals for solutions 2:

Structural investment in methodological supervision of such research. Quality control of the research prior to implementation by veterinary-ethical review boards. Monitoring publications on conducted trials by veterinary-ethical review boards. Implementation of outcome research by reputable research institutes. Development of structural cooperation between reputable research institutes and the practice of 'homeopathic treatment' (farmers and veterinary practitioners) so that good research can be set up and carried out which ties in with the specific practice of homeopathic treatment.

5.3. Individual nature of homeopathic treatment

Obstacle 3: Current developments in Evidence Based Medicine within the framework of improving quality in professional performance threaten to impose protocols for specific indications on homeopathic practice. This may in part be to the detriment of the individual nature of homeopathic treatment and thus also reduce rather than improve the quality of treatment.

Proposals for solutions 3: Development of new and application of new and existing quality instruments which do justice to the individually tailored nature of homeopathic practice. The primary considerations here are (a) training the judgement of the individual therapist and (b) the use of 'casuistic' methods of (outcome) research (see below), which will do justice to the individualised selection of therapies.

5.4. Incorporating experiential knowledge

Obstacle 4: The use of what is usually implicit experiential knowledge is in many cases an essential part of the homeopathic approach to treatment and on the face of it is not accessible to research.

Proposals for solutions 4:

Use the 'black-box' approach in outcome research in which the therapist can carry out the optimum treatment in his/her own way. Outcome research is designed around this. Make experiential knowledge explicit by means of research with the aid of 'consensus methods' (Swanborn, 1999). Development of new ways to make this experiential knowledge transferable and so more accessible to fundamental and evaluation research.

5.5. Need for supplementary outcome evaluations

Obstacle 5: Often, because of the partly individual nature of homeopathic practice, current research methods of evaluating the effect of treatment can be inadequate.

Proposals for solutions 5: There are two sides to the solution to this problem. The first is perfectly illustrated in the work of Kramers (1998), in which he discusses new research designs, often developed in conventional health care, which take account of various aspects of complementary treatment practice. However, this approach is based on the same principles of outcome research as used in the experiment. For example an open three-armed randomised trial with free choice of therapy or the COLA (Change to Open Label) procedure.

The second relates to an entirely new approach to outcome research within the framework of a vision of 'Cognition Based Medicine' (Kiene, 1998; 2001) and is based on the possibility of recognising a 'Gestalt' in the development of unique patterns. These methods were developed specifically for outcome studies of the more individualised forms of health care such as we find particularly in complementary health care. This methodological approach ties in directly with the individual doctor or therapist's ability to use his/her own judgement.

To give a clear understanding of the difference and basis of this casuistic outcome research we will briefly describe the two approaches in relation to each other.

5.5.1. Randomised Clinical Trial versus Therapeutic Causality Report

Outcome research is in the first instance carried out to determine causal relationships between interventions and subsequent effects ('is the effect the result of my intervention based on the remedy administered or the treatment given?'). In this form of research the randomised double blind trial method (RCT) is generally regarded as the gold standard. In addition to various forms of criticism of the method itself (Kiene, 2001), there are manifest limitations to the research results obtained by this method for use in health care practice. Kaasenbrood (1998) writes: 'the tension between evidence-based psychiatry and day to day practice can essentially be interpreted as the tension between science and practice.' and 'The issue of whether the treatment methods whose usefulness has been demonstrated by scientific research are also the best methods for the specific situations of individual patients in general treatment practice is far from being resolved.' The tension referred to above is also present in many forms of complementary health care. One of its specific features is that their ideal is not to arrive at standard solutions to standard problems. They often strive for a situation in which the therapists and carers can independently arrive at individual solutions suited to the specific situation of the patient based on general insight into the condition and the specific elements of the situation. To do justice to this idea in outcome research various people have worked over the past decade on the development of new research methods for outcome research. The Therapeutic Causality Report (TCR) (Kiene, 1998, 2001) makes it possible to determine the effect of a treatment based on just one or a few cases without disrupting clinical practice (including the situational treatment of the individual patient). In the next section we come to the principles of RCT and TCR in connection with the issue of causality.

The Randomised Clinical Trial: a 'per exclusionem' method

The issue of internal validity is central to outcome research. It revolves around whether one knows with certainty that the observed effect was determined by the therapeutic intervention alone, and not by something else. Professor of Epidemiology Bouter (Bouter and Van Dongen, 1995) states that the observed effect of an intervention is in principle made up of four different parts:

- (a) the specific effect of the intervention,
- (b) the natural course of the complaint,
- (c) the external variables which influence the effect of the intervention (confounders and/or effect modifiers),
- and
- (d) errors made in measuring the effect.

The methodology and statistics used in a trial or research project aim as far as possible to control for the three non-specific effects (b), (c) and (d). Thus in the therapeutic experiment or the randomised clinical trial (RCT) there should if possible be two groups, and the only difference between the groups is that there is therapeutic intervention in the experimental group while the control group is given a placebo or existing intervention. The ultimate difference in observed effect between the two groups is then only attributable to the therapeutic intervention (with placebo control) or the added value of the experimental intervention (with control using an existing intervention). The determination of the specific effect of the intervention is based on the exclusion (as far as possible) of all other possible influences (= 'per exclusionem').

TCR: the positive identification method¹⁰

Just as RCT is characterised by 'the exclusion of the possibility that something else caused the effect', TCR is characterised by the positive identification of the **originator** of the subsequent effect. This form of outcome research makes it possible in a single case or a few cases to establish a causal relationship based on the occurrence of unique patterns and the establishment of the correspondence in unique patterns¹¹, which becomes visible in the 'Abbildungs Korrespondenz' or 'pictural correspondence' (Kiene, 1998). This correspondence makes it possible to establish a causal relationship in a positive way: not by excluding all other possibilities, but by certain recognition of the 'originator'. The singularity of the pattern, the transference of this pattern by the therapist or scientist (the 'Abbildungsprozess') and the determination of the correspondence in unique pattern play a central methodological role in this process. In casuistic outcome research this principle is used in various different ways by distinguishing, for example, spatial, time, process and theory patterns (Kiene, 1998; Baars, 1997; Baars, 2000) (see below).

Example of the spatial aspect

The following description is idealised, but something similar happened in clinical reality:

After a patient had suffered for several weeks with an extensive skin irritation, a salve was applied in the forms of an S. Within three days the irritation went away in the S shape, precisely where the salve had been applied. The salve was then applied over the entire area of irritated skin, and after another three days the irritation was entirely gone.

This idealised anecdote paints an interesting and complex situation, because different elements play a role in the evaluation of the therapy: the first is the healing of the S-shape directly after applying the therapy, within three days. In comparison with the timespan for the therapeutic intervention this timespan of three days is very short, which is a strong indication of therapeutic causality. The second and most convincing aspect is the correspondence in spatial form (the S-shape) between the application of the salve and the healing process. The third element is the repetition of the healing process of three days, now over the entire area. These three elements taken together provide very strong grounds for determining causality. The therapeutic success could

¹⁰ Texts by Kiene (1998) and Baars (2000)

¹¹ An example in which the recognition of unique patterns was implicitly used is that of a typewriter shop. In the fight against crime the shop owners were regularly called upon to examine letters typed by criminals. They typed the letters to avoid having their handwriting recognised. However, what the criminals overlooked was the fact that typewriters have specific shape characteristics. An initial study of a letter revealed that the different letters each had a specific shape, for example an 'a' with a curlicue above. This rapidly led to the conclusion that the typewriter used was one of a particular series built by a particular factory. If the typewriter was not entirely new it was also possible to identify small, typical changes in the typed characters. For example, the top of the 't' might be a little lighter than the rest of the letter and the 'd' always rotated slightly to the left, etc. Thus a unique pattern was built up from a combination of small deviations. Consequently, the typed letter could only have been typed on one typewriter and no other. The sum of the unique combination of deviations in the keys of the typewriter was portrayed in the letter. There was a correspondence in the unique pattern (between typewriter and letter), from which the 'originator' of the letter could be identified.

even be repeated in a single patient: what would otherwise have required two randomised trials could be achieved within the treatment of a single patient.

Example of the time aspect: long before versus shortly after

Another important guide can be found in the timespan of an illness (or symptom) before and after intervention. If a symptom has existed for a long time and disappears shortly after therapy, that indicates the efficacy of the treatment. If a patient has been ill for 15 years, and then recovers within four weeks, that is a completely different case than that of a symptom duration of five weeks before and four weeks after therapy. If there is immediate relief within seconds, that is of course convincing. Where there is doubt, it makes sense not to base the determination on a single patient but on a group of, say, five unselected patients. If there is always a long before and shortly after scenario, it is increasingly likely that the effect can be attributed to the intervention.

Example of the therapeutic idea

A very simple example of a representation of a therapeutic idea can be found in the tracheotomy or incision of the windpipe when there is a mechanical blockage in the upper airways. In this case the therapeutic idea is as follows:

Thanks to current knowledge of the anatomical and physical structures and processes of the organism we understand fully that if the upper airways are mechanically blocked for example by a swelling, the person concerned will choke. On the other hand, based on the same knowledge, we also fully understand that in the case of such a mechanical blockage and difficulty in breathing, treatment by means of an incision in the windpipe can save the person's life.

If the tracheotomy is successful, there cannot be the slightest doubt about its efficacy – Why is doubt ruled out? –First of all, the scalpel used in the tracheotomy, i.e. in the therapeutic treatment, is used immediately before the creation of the incision-shaped neck and windpipe opening, whereby the shape of the scalpel is represented in that of the incision and that immediately after that we observe that the patient no longer has difficulty in breathing. Secondly, however, and no less importantly, we have full insight into how and why the acute difficulty in breathing can be alleviated by a tracheotomy. Then there is a third and *fully transparent* insight which we will refer to here as a *therapeutic idea*. This therapeutic idea is actually transposed to the organism, or reflected onto it by the associated therapeutic treatment.

In this case the therapeutic idea is so clear and transparent that the therapeutic efficacy of the tracheotomy finally seems trivial. For this reason no-one would wish to demonstrate the efficacy of this treatment of an emergency case by replicating it, never mind by conducting randomised trials. However, one might always demand that the person performing the operation should meet the necessary conditions and be in the profession: in other words that it would be performed by someone with precise knowledge of the anatomical proportions of the larynx who can carry out the tracheotomy with precision.

5.5.2. Scientific underpinning of TCR

The outcome research and casuistics approach is supported by the work of Swanborn (2000) on case studies. He specifies two elements which increase the power of expression of casuistic statements, namely increasing the amount of data or observations and working with expectations or predictions as a way of testing the concept or theory. He writes (p. 93): 'Historians have come up with at least 25 different explanations for the French Revolution. We could say that there are more explanations than facts.' This is an example of the basic weakness and criticism of this branch of methodology: the material of a case study permits of very many interpretations, and we do not have the means to make a responsible selection from this multiplicity. In other words we do not know which theory gives the right explanation of the facts. Swanborn's solution to this problem lies in increasing the 'number of data points'. He maintains that this can be done effectively by increasing the number of points at which measurements are taken or increasing the number of predictions. This 'intervention' creates a situation in which more facts have to be explained by a theory. *'There is then as it were a greater risk that the theory will not fit; it is difficult to find a theory which fits that is still not extremely complicated.'* In short; by collecting more data we create the means to choose a theory which can best explain the established facts. We can then make this choice because the theory must fit: the facts and the explanatory theory must correspond.

The way this works in practice becomes clear in the elaboration of the term 'increasing the number of predictions'. Swanborn writes: *'From every theory, from every model, it is possible to derive a greater or lesser*

number of predictions, which can be tested against the data of the cases themselves.' ... 'If in addition we think up a few alternative interpretations beforehand and also mould the consequences of these into predictions, we have a strong case if the predictions are not borne out. If such a pattern occurs it is difficult to attribute the changes to anything other than the intervention.' ... 'The more independent predictions are borne out, and the fewer predictions from alternative theories are borne out, the stronger the case for a causal relationship.' The analysis of this methodology is called *pattern matching*. What it comes down to is that *'the score pattern on a number of variables at a time is compared with a previously predicted pattern.'* *'The more extensive (complete, complex) the predicted pattern, the more rigorously the hypothesis is tested.'* The *methodological principle* of pattern matching used here can be recognised as a form of 'Abbildungs Korrespondenz' or 'pictorial correspondence': the establishment of the correspondence in a unique pattern. We also see links to these case study methods in, say, empirical research into archaeology and evolution. Here we are without any experimental argument and almost exclusively use pattern recognition from which we can derive unique relationships.

Causality and plausibility

Causal relationships cannot be proven, either by logic or statistics. For a proof we need irrefutable statements and such statements are not possible in the empirical sciences (Nagel 1971; Rothman and Greenland 1998). The best one can achieve in these sciences is to make a plausible case. For causal relationships there must be a plausible argument both that there really is an association and that the association is causal in nature. The arguments in this context may be very varied in nature: from substantive to formal-logical, statistical and methodological. In the debate about the causal relationship between smoking and health Hill (1965) formulated a list of points which can be used in epidemiological studies in arguments for or against the causal nature of an observed association. Campbell and Stanley (1966) and Cook and Campbell (1979) carried out radical methodological analyses of the tenability or otherwise of causally formulated conclusions of experiments and quasi-experiments.

Hill's list has recently been adapted in response to commentary (Ormel and Kluitert, 1999) and now includes the following arguments of a methodological-statistical nature (2, 3, 4, 5, 6 and 7) and substantive or formal-logical (1, 8, 9 and 10): (1) sequence in time, (2) statistical significance and statistical error of the first kind, (3) potency of effect, (4) reliability and validity of measurements, (5) internal validity, (6) external validity, (7) ecological validity, (8) biological, psychological and/or social gradient, (9) compatibility with the state of (knowledge in) biology, psychology and/or sociology, (10) reaction to manipulation. The authors close their argument with the conclusion: 'A critical analysis of the list reveals that not a single point in itself nor any single combination of points is of overriding importance to the plausibility of a causal relationship. Reproducibility in replicated trials (see points 2, 6 and 7) is in practice the most important criterion for recognising the existence of an association. This criterion has nothing more to say about causality. Seen in strictly logical terms, only the point of the sequence in time is a necessary condition for an association to be causal. Reaction to manipulation is also necessary (but not sufficient), but only applies if manipulation is possible, which is rarely the case. All other points are neither necessary nor sufficient. That is certainly not to say that they are not important. Thus, as we have said, testing of the data on the association against these or any other list never leads to conclusive proof. *'The best one can achieve is to make a plausible case for causality.'*

5.5.3. Causality in RCT and TCR

With causality it is thus primarily a matter of making it increasingly plausible that there is a causal relationship between intervention and a subsequent effect. It is clear from the above that RCT and TCR take different routes and use different arguments to make this relationship credible. In *RCT* this relates to the following aspects:

- (a) reproducibility of the occurrence of an effect in replicated trials is the most important criterion to make a plausible case for an association;
- (b) the exclusion or control of other aspects which could influence the outcome in a comparative experiment make it plausible that the subsequent difference between the control and experimental groups can be attributed to the intervention being investigated; and
- (c) the risk calculation which makes it plausible that the differences which occur are not just coincidental.

In *TCR* a plausible case is made for a causal relationship by positively recognising the originator with certainty. The following factors play a central methodological role:

- (a) the singularity of the pattern,
- (b) the transference of this unique pattern by the therapist or scientist (the 'Abbildungsprozess'), and
- (c) the establishment of the correspondence in unique pattern.

5.5.4. Research design to determine the effects of homeopathic treatment

There are generally two reasons for carrying out outcome research. The first is to justify the method of treatment to the external world (health insurers, scientists, sceptics, etc.). A second reason concerns the ability of the doctor or therapist to professionally pursue and steer the therapeutic process. At each stage of the treatment the central question is: is my therapeutic treatment effective or should I adjust it?

If the issue is the external justification of a treatment method, there are numerous research designs available, which can be used in different situations. The treatment methods all have their advantages and disadvantages and methods are selected by weighing up the pros and cons of the different methods. For example, a selection criterion might be the extent to which there is control for distortion ('bias') within the method (RCT scores highest on this point with the quasi-experimental research design slightly lower). For this criterion use is generally made of a generally accepted list, in which the research methods are ranked according to the extent of controls for bias (WHO, 1998; Cochrane Collaboration, 2002). *TCR* and other new methods are not included in these lists because they are not as yet as well known. Another selection criterion might be the extent to which the method permits of individually tailored treatment (as for example is the case in the 'black-box method' and in *TCR*). A third criterion might be the cost of a trial (an RCT often costs far more than *TCR*).

At international level the following institutions are working to validate homeopathic treatments of animals by means of outcome research¹²:

- FiBL (Switzerland) has a programme in which it both investigates the effects of potentised remedies on cell growth and conducts clinical trials on the effects of homeopathic remedies on domestic pets and farm animals (www.Fibl.Ch) (Spranger and Klocke, 2000; Anon., 2001).
- In Italy there are several colleges of homeopathy (Martini *et al.*, 2001). Two of these specialise in veterinary homeopathy (the Scuola Superiore Internazionale di Medicina Veterinaria Omeopatica in Cortona and the Accademia Italiana di Omeopatia Veterinaria).

If the reason for the outcome research is to enable a doctor or therapist to pursue the therapeutic process, then *TCR* can be used. Ideally *TCR* should be structurally embedded in a larger research infrastructure consisting of collaboration between research institutes, veterinary practitioners and farmers. Within this collaborative framework constructive work can be carried out on:

- Exploring the experience of veterinary practitioners and farmers with homeopathic treatments of animals
- The methodical exchange of this experience and subsequently reaching consensus about general guidelines for the homeopathic treatments for various indications
- Evaluation of the effect of the general guidelines for homeopathic treatments for various indications with the aid of *TCR*
- Learning to use case study methods (including *TCR*) which can be applied in the individualisation of homeopathic treatments
- Evaluation of the effect of individualised homeopathic treatments with the aid of *TCR*
- (Possible) Evaluation of the effect of homeopathic treatments (possibly in comparison with other treatment methods) with the aid of larger clinical trials using, say, RCTs.

In this way we can give due weight to the experience of veterinary practitioners and farmers and homeopathic treatment practice with its tailored solutions, and outcome research can become an integral part of the working methods of veterinary practitioners and farmers.

¹² Further information on regional groups working in homeopathy can be found on the website of the International Association for Veterinary Homeopathy: www.iavh.at

5.6. Beyond the bounds of matter

Obstacle 6: Many people reject homeopathy a priori on theoretical grounds. It is regarded as ineffective from the ontological reductionist point of view, which is that there can be no efficacy beyond certain dilutions (Avogadro's number) due to the lack of material molecules in the solution administered.

Proposals for solutions 6:

We need to communicate better in both the social and scientific debates that the above point of view is based on and originates in a theoretical model which, like every other model, can and must be tested for validity (Oost, 1999).

More scientific attention must be paid to the scientific argument which casts doubt on the ontological reductionist view.

In the scientific debate further research is required on compatibility with the current state of the science of both the ontological reductionist and the ontological holistic explanatory model.

5.7. Prior testing of quality or potential efficacy of the remedy

Obstacle 7: It is not clear whether the quality or potential efficacy of homeopathic remedies supplied by the pharmaceutical industry is always consistent. This could cause distortion (bias) in replicated trials in outcome research¹³.

Proposals for solutions 7:

Within the 'research chain' the quality and potential efficacy of homeopathic medicines must be established by means of validated verification systems prior to the actual empirical outcome research. Particular consideration must be given to research methods which are appropriate to the singular nature (force) of such remedies, including conceptualising methods.

5.8. Developing a research infrastructure in the Netherlands

Obstacle 8: The Netherlands currently lacks an adequate research infrastructure for research into homeopathy in livestock farming. Nor is there a strategic approach to research which is compatible with the singular nature of the underlying complementary health and welfare concept.

Proposals for solutions 8:

Research should be appropriate to the individualised nature of the treatment. In practice sufficient alternative methodologies have been developed which can be used in outcome research. The researchers therefore propose the following graduated structure for outcome research:

1. Continuous monitoring of the experience of veterinary practitioners and farmers with all homeopathic treatments.
2. Low budget TCR on a few promising treatments for specific indications which emerge from the monitoring project referred to under (1).
3. Model projects in which the individualised approach of homeopathic treatments is further developed through planning, process and product evaluation (Swanborn, 2000) and tested for effectiveness.
4. Model projects in which homeopathic treatments form part of an overall complementary approach to certain diseases.
5. Theoretical research into the validity of underlying and adjoining concepts of, inter alia, the working mechanisms of these types of remedies, holism versus reductionism, (health through) self-regulation, and life.

¹³ See for example: Andersson and Leon, 1999

5.9. Development of vocational training in veterinary medicine

Obstacle 9: In contrast with some other European countries the Netherlands lacks adequate training courses for homeopathic veterinary practitioners. Furthermore in the current educational system veterinary practitioners are trained by doctors working in human health care. There is no research policy aimed at evidence-based support for a course in homeopathic veterinary medicine.

Proposals for solutions 9:

Efforts must be made to introduce essential training within the current veterinary medicine course at the University of Utrecht. Lecturers should be sought among qualified veterinary homeopaths. University research policy should be in line with this training.

6. Conclusions and recommendations

Erik Baars and Ton Baars

The aim of this desk study was in the first instance to arrive at an overview of existing research in homeopathy, in terms of both results and research methodology. A second aim was to gain insight into the way in which new research into the use and efficacy of homeopathic remedies could be used in organic livestock farming.

Proof of effectiveness of homeopathy

To sum up we can conclude on methodological grounds that as yet the evidence to establish the effectiveness of the remedies in general and for specific indications is poorly presented. In concrete terms this means that there is still insufficient empirical evidence of the effects of homeopathic treatments. On the other hand there are sufficient empirical indications concerning both forms of medication to justify effectiveness and further research.

New research into the use and efficacy of homeopathy

Good follow-up research should be in line with the underlying complementary health and welfare concept which encompasses treatment with this type of remedy. RCTs are thus of limited use, since they disregard the individualised character of the treatment. In practice however sufficient alternative methodologies have been developed which can be used in outcome research. We therefore propose the following graduated structure for outcome research:

1. Continuous monitoring of the experience of veterinary practitioners and farmers with all homeopathic treatments. Working method: use existing short standard questionnaire. This requires little effort and is completed by the veterinary practitioner and the farmer (Evans and Zimmerman, 2003, submitted). Result: (a) experience-based overview of potentially effective homeopathic treatments, (b) an initial form of feedback to veterinary practitioners, farmers and policy makers.
2. Low budget TCRs into a few promising treatments for specific indications which emerge from the monitoring project referred to under (1). Result: Good, low budget results of outcome research.
3. Model projects in which the individualised approach of homeopathic treatments is further developed through planning, process and product evaluation (Swanborn, 2000) and tested for effectiveness. Result: evaluation of an optimum homeopathic approach to treatment.
4. Model projects in which homeopathic treatments form part of an overall complementary approach to certain diseases. Within these model projects comparative studies are carried out to examine whether there is added value in homeopathic treatments which form part of an overall complementary approach, compared with a solitary homeopathic treatment. Result: insight into the role of the context within which homeopathic treatments are given for the effect of those treatments.
5. Some 'state of the art' Randomised Controlled Trials (RCTs) for those promising general treatments for general indications. Result: some results which can withstand the test of scientific criticism.
6. Theoretical research into the validity of underlying and adjoining concepts of, inter alia, the working mechanisms of these types of remedies, holism versus reductionism, (health through) self-regulation, and life. Result: specific knowledge required for scientific and social acceptance of the effect of these types of medication obtained by empirical research.

Other conditions which must be met by good outcome research include:

1. Additional quality control of the remedies so that outcome research can assume optimum effectiveness of the remedy concerned. For example, the use of validated 'conceptualising' methods such as the crystallisation method (Andersen *et al.*, 2001).
2. The creation of a research infrastructure or complementary health care network in which veterinary practitioners, farmers, policy makers and researchers participate in joint policy-making and implementation.
3. The outcome research should be performed or supported by qualified researchers who are prepared to base work on a more holistic and complementary approach.
4. Training and courses in homeopathy need to be improved.

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