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SCIENTIFIC FRAMEWORK OF HOMEOPATHY

Evidence Based Homeopathy 2012

Revised edition after 66th LMHI Congress, December 2011 (New Delhi, India)



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SUMMARY

This booklet is aimed at considering all important aspects of the scientific framework of homeopathic practice including ethical questions and evaluation of daily practice, looking at the level of scientific evidence of each of these aspects. The conclusions are that homeopathy has to stay in the framework of medical practice and it is even a necessity for public health. Of course, more research is always necessary.

This booklet is a joint production of the Liga Medicorum Homoeopathica Internationalis and of the European Committee for Homeopathy.

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CHAPTER I

INTRODUCTION

The aim of this booklet is the study of the current framework of the practice of homeopathy in the world. The scientific adequacy will be considered regarding the level of positive evidence currently available for each considered aspect.

The comparable Oxford university scale is divided into five levels instead of four.

Level of evidence :

- I = the existence of meta-analyses and/or systematic positive « reviews » of the literature.
- IIa = controlled multiplied experiments, randomised, positive results.
- IIb = some controlled experiments, randomised, positive results.
- IIIa = study with multiple cohorts, positive results.
- IIIb = study with some cohorts, positive results.
- IV = opinion of experts (clinical and daily cases)

The use of homeopathic medicines is widely spread throughout the world population.

In Europe and some other countries in the world, these medicines are submitted to a registration procedure (1) that guarantees an optimal pharmaceutical quality and safety for users.

A potential risk may exist when these medicines are used without having already made a medical diagnosis. To minimize this risk it is essential to keep homeopathy within the framework of medical practice.

In several countries, a law on patients' rights has come into force. This means that the patients have the right to choose or to refuse a proposed treatment. Medical doctors cannot inform the patient correctly if they do not know all possible medical approaches. As such, an ethical dilemma is created when the use of homeopathic medicines would warrant consideration and Medical Doctors are not aware of the possible efficiency of homeopathic treatments.

It is essential for public health to formulate concrete answers to all of these questions. This booklet is also aimed to help in the formulation of pragmatic solutions to these problems.

CHAPTER II

GENERAL FRAMEWORK AND ETHICAL POINT OF VIEW (2)

First part of chapter II

A. The place of the non-conventional medicine in our public health system

The **World Health Organisation (WHO)** concludes, in a report of May 2005, concerning the politics surrounding traditional medicine in different countries (3), that traditional medicine (TM), all over the world, maintains its popularity. In addition, during the last ten years the use of CAM (Complementary and Alternative Medicine) has increased in several countries. The safety of the use of these products and their quality control and evaluation in term of efficacy are priorities for the political authorities as well as for the population.

The WHO questioned their 191 members. Of those 141 countries (74 %) responded. Of these countries who responded, 32 % have developed a policy of health including TM/CAM and 56 % stated that a policy concerning TM/CAM is in "construction".

Only 5 countries developed this regularization prior to 1990.

Of those responders, 28 % have an adapted national program specific to TM/CAM and 58 % have put in place a national committee responsible for TM/CAM. In most cases this committee is part of the Health Department. Of these responding countries 43 % have established a committee of experts for TM/CAM.

A problem of harmonization exists among the different countries. This may be attributed to major difficulties such as the absence of a standardized educational program for TM/CAM and a lack of experts on this matter. Countries are asking the support and advice of the WHO to develop a national policy concerning the regularization of TM/CAM.

Beijing Declaration

Adopted by the WHO Congress on Traditional Medicine, Beijing, China, 8 November 2008

Participants at the World Health Organization Congress on Traditional Medicine, meeting in Beijing this eighth day of November in the year two thousand and eight:

- Recalling the International Conference on Primary Health Care at Alma Ata thirty years ago and noting that people have the right and duty to participate individually and collectively in the planning and implementation of their health care, which may include access to traditional medicine;
- Recalling World Health Assembly resolutions promoting traditional medicine, including WHA56.31 on Traditional Medicine of May 2003;
- Noting that the term "traditional medicine" covers a wide variety of therapies and practices which may vary greatly from country to country and from region to region, and that traditional medicine may also be referred to as alternative or complementary medicine;
- Recognizing traditional medicine as one of the resources of primary health care services to increase availability and affordability and to contribute to improve health outcomes including those mentioned in the Millennium

Development Goals;

- Recognizing that Member States have different domestic legislation, approaches, regulatory responsibilities and delivery models;
- Noting that progress in the field of traditional medicine has been obtained in a number of Member States through implementation of the WHO Traditional Medicine Strategy 2002-2005;
- Expressing the need for action and cooperation by the international community, governments, and health professionals and workers, to ensure proper use of traditional medicine as an important component contributing to the health of all people, in accordance with national capacity, priorities and relevant legislation;

In accordance with national capacities, priorities, relevant legislation and circumstances hereby make the following Declaration:

- I. The knowledge of traditional medicine, treatments and practices should be respected, preserved, promoted and communicated widely and appropriately based on the circumstances in each country.
- II. Governments have a responsibility for the health of their people and should formulate national policies, regulations and standards, as part of comprehensive national health systems to ensure appropriate, safe and effective use of traditional medicine.
- III. Recognizing the progress of many governments to date in integrating traditional medicine into their national health systems, we call on those who have not yet done so to take action.
- IV. Traditional medicine should be further developed based on research and innovation in line with the "Global strategy and plan of action on public health, innovation and intellectual property" adopted at the Sixty-first World Health Assembly in resolution WHA61.21 in 2008. Governments, international organizations and other stakeholders should collaborate in implementing the global strategy and plan of action.
- V. Governments should establish systems for the qualification, accreditation or licensing of traditional medicine practitioners. Traditional medicine practitioners should upgrade their knowledge and skills based on national requirements.
- VI. The communication between conventional and traditional medicine providers should be strengthened and appropriate training programs be established for health professionals, medical students and relevant researchers.

At the sixty-second World Health Assembly of 22 May 2009 (WHA62.13 – Agenda item 12.4 about Traditional medicine) the WHO concluded as follow:

Having considered the report on primary health care, including health system strengthening (Document A62/8); Recalling resolutions WHA22.54, WHA29.72, WHA30.49, WHA31.33, WHA40.33, WHA41.19, WHA42.43, WHA54.11, WHA56.31 and WHA61.21; Recalling the Declaration on Alma-Ata which states, inter alia, that “The people have the right and duty to participate individually and collectively in the planning and implementation of their health care” and “Primary health care relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community”;

Noting that the term “traditional medicine” covers a wide variety of therapies and practices which may vary from country to country and from region to region;

Recognizing “traditional medicine” as one of the resources of primary health care services that could contribute to improved health outcomes, including those in the Millennium Development Goals;

Recognizing that Member States have different domestic legislation, approaches, regulatory responsibilities and delivery models related to primary health care;

Noting the progress that many governments have made to include “traditional medicine” into their national health care;

Noting that progress in the field of “traditional medicine” has been achieved by a number of Member States through implementation of the WHO traditional medicine strategy 2002-2005 (Document WHO/EDM/TRM/2002);

Expressing the need for action and cooperation by the international community, governments and health professionals and workers, to ensure proper use of “traditional medicine” as an important component contributing to the health of all people, in accordance with national capacity, priorities and relevant legislation;

Noting that the WHO Congress on “Traditional Medicine” took place from 7 to 9 November 2008, in Beijing, China, and adopted the Beijing Declaration on “Traditional Medicine”;

Noting that African Traditional Medicine Day is commemorated annually on 31 August in order to raise awareness and the profile of “traditional medicine” in the African region, as well as to promote its integration into national health systems,

1. URGES Member States, in accordance with national capacities, priorities, relevant legislation and circumstance:

(1) to consider adopting and implementing the Beijing Declaration on Traditional Medicine in accordance with national capacities, priorities, relevant legislation and circumstances;

(2) to respect, preserve and widely communicate, as appropriate, the knowledge of traditional medicine, treatments and practices, appropriately based on the circumstances in each country, and on evidence of safety, efficacy and quality;

(3) to formulate national policies, regulations and standards, as part of comprehensive national health systems, to promote appropriate, safe and effective use of traditional medicine;

(4) to consider, where appropriate, including traditional medicine into their national health systems based on national capacities, priorities, relevant legislation and circumstances, and on evidence of safety, efficacy and quality;

(5) to further develop traditional medicine based on research and innovation, giving due consideration to the specific actions related to traditional medicine in the implementation of the Global strategy and plan of action on public health, innovation and intellectual property;

(6) to consider, where appropriate, establishing systems for the qualification, accreditation or licensing of traditional medicine practitioners and to assist traditional medicine practitioners to upgrade their knowledge and skill in collaboration with relevant health providers, on the basis of traditions and customs of indigenous peoples and communities;

(7) to consider strengthening communication between conventional and traditional medicine providers and, where appropriate, establishing appropriate training programmes with content related to traditional medicine for health professionals, medical students and relevant researchers;

(8) to cooperate with other in sharing knowledge and practices of traditional medicine and exchanging training programmes on traditional medicine, consistent with national legislation and relevant international obligations;

2. REQUESTS the Director-General:

(1) to provide support to Member States, as appropriate and upon request, in implementing the Beijing Declaration on Traditional Medicine;

(2) to update the WHO traditional medicine strategy 2002-2005, based on countries' progress and current challenges in the field of traditional medicine;

(3) to give due consideration to the specific actions related to traditional medicine in the implementation of the Global strategy and plan of action on public health, innovation and intellectual property and the WHO global strategy for prevention and control of non communicable diseases;

(4) to continue providing policy guidance to countries on how to integrate traditional medicine into health systems, especially to promote, where appropriate, the use of traditional/indigenous medicine for primary health care, including disease prevention and health

promotion, in line with evidence of safety, efficacy and quality taking into account the traditions and customs of indigenous peoples and communities;

(5) to continue providing technical guidance to support countries in ensuring the safety, efficacy and quality of traditional medicine; considering the participation of peoples and communities and taking into account their traditions and customs;

(6) to strengthen cooperation with WHO collaborating centres, research institutions and non governmental organizations in order to share evidence-based information taking into account the traditions and customs of indigenous peoples and communities; and to support training programmes for national capacity building in the field of traditional medicine.

Eighth plenary meeting, 22 May 2009

A62/VR/8

WHO Safety Issues in the Preparation of Homeopathic Medicines 2010

This official WHO booklet is considering the challenges of quality control and regulation of homeopathic medicines in the world. It can be requested at bookorder@who.int under ISBN number 978 92 4 159884 2 (NLM classification: WB 930). It may be downloaded at www.who.int/medicines/areas/traditional/prehomeopathic/en/index.html.

It defines homeopathy as one of the most commonly used form of herbal medicines (*even if plants are not the only stocks used in homeopathy*). There is a large market for homeopathic products around the world. For example, in 2008, Australia spent 7.3 million US dollars on homeopathic medicines, France spent more than 408 million, Germany 346 million and the United Kingdom more than 62 million US dollars. In the United States, adults spent 2.9 billion US dollars on homeopathic products in 2007.

The use of homeopathic medicines has spread more and more, and now it is widespread, not only in the European region, but also in south Asian countries and North and South American countries. With the worldwide increase in the use of homeopathic medicines and the rapid expansion of the global market, the safety and the quality of homeopathic medicines has become a major concern for health authorities, pharmaceutical industries and consumers. The safety of the homeopathic medicines largely depends on their quality. Requirements and methods for the quality control of finished homeopathic medicines are far more complex than for chemical drugs, particularly for the combined or mixed homeopathic medicines. Furthermore, the quality of the homeopathic medicines is influenced both by the quality of the procedure used

during their production and the quality of the raw material. Products that meet high quality standards are needed to allow the patient to make safe use of the homeopathic medicines. Now, this is more and more important because, as a consequence of market globalization, many of the raw materials and medicines used in the homeopathic systems come from different countries.

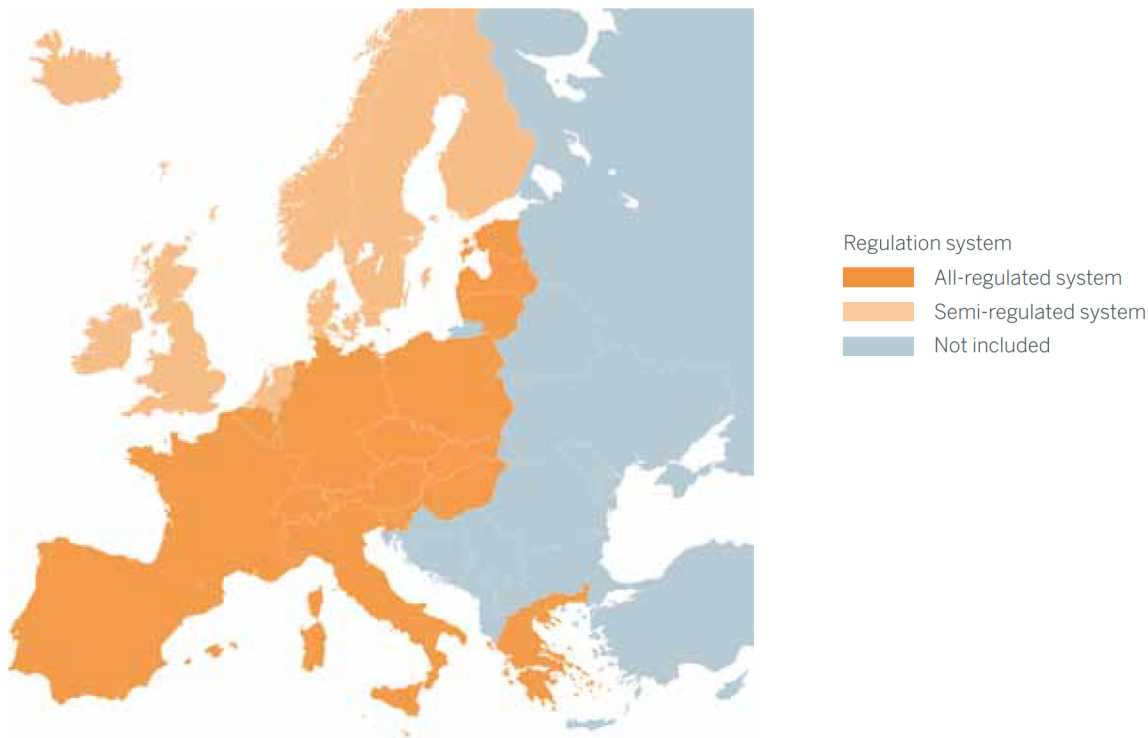
Adverse events occurring during homeopathic treatment are rarely attributed to the homeopathic medicine itself. However, safety assessment should also consider possible impurities of the source material or contamination in production and failures of good manufacturing practice. Furthermore, because many homeopathic medicines can be purchased as non-prescription medicines in community pharmacies and health stores, without consultation with a healthcare provider, it has become increasingly important to provide sufficient and accessible information regarding such medicines. Although homeopathic medicines are generally assumed to be benign, the level of authorization, appropriate labelling and quality assurance should take into consideration their extensive use, including that within vulnerable populations such as the elderly, pregnant women and children.

In **Europe** the report "Concerted Action for Complementary and Alternative Medicine (CAM) Assessment in the Cancer Field" (4) observed the same tendency concerning an increase in the use of CAM. This evolution goes on in different countries within different scientific frameworks. CAM would be understood as Non Conventional Medicine meaning that it is not yet part of a Convention in Medicine. This situation could evolve in the future.

Diagram 1: Regulation in European countries (CAM-CANCER report).

	« fully controlled systems » n=19	« partial controlled systems » n=10	
Countries	Austria, Belgium, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Latvia, Lithuania, Luxembourg, Italy, Poland, Portugal Spain, Slovenia, Slovakia, Switzerland,	Denmark, Finland, Iceland, Liechtenstein, Irland, Malta, The Netherlands, Norway, Sweden, UK	
Who is allowed to treat?	Statutorily regulated individuals.	Statutorily regulated individuals.	Everybody
Authorized Medical Activities:	<ul style="list-style-type: none"> • “risky” medical procedures • treating serious diseases • safe medical procedures • preventive/prophylaxis 	<ul style="list-style-type: none"> • “risky” medical procedures • treating serious diseases • safe medical procedures • preventive/prophylaxis 	<ul style="list-style-type: none"> • safe medical procedures • preventive/prophylaxis

Regulation systems in Europe



In 19 of the 29 European countries (Central and South Europe) only the statutorily regulated individuals have the legal authorization to treat patients. In the ten remaining countries (Northern Europe) non-statutorily regulated individuals can offer care. In these countries several responsibilities remain in hands of medical doctors. The authorities control CAM practices by a “permit to practice”, a licence, a protected title or voluntary registration. A supervising commission is installed in these countries. This commission determines which type of CAM can be considered as “sound professional practice” when delivered by statutorily regulated individuals. The practice by statutorily regulated individuals is strictly limited in some countries whereas in other countries these statutorily regulated individuals can have a free, unlimited practice.

“Plants” and homeopathic medicines authorized on the market are controlled by specific European directives and these directives are implemented in national legislation.

How can we protect patients from treatment inadequacy? The best way would be the recognition of CAM treatments in an adequate and legal way, but questions remain: is it better to limit the practice of CAM to accredited persons (Central and South Europe) versus non-accredited persons (Northern Europe)? Is the efficacy and quality of the CAM sufficiently verified in order to consider its introduction in the healthcare systems?

Table 2: regulated CAM in different European countries.

X: year of legalisation unknown.

Y: new law in preparations.

Countries	Regulating CAM providers by law								License	CAM Register
	No	Yes								
		Chiro- practics	Osteo- pathy	Napra- pathy	Homeo- Pathy	Acu- puncture	Naturo- -pathy	Phyto- therapy		
Austria	no									
Belgium		1999	1999		1999	1999				
Bulgaria					2005					
Cyprus		X	y			y				
Czech Republic					2002					
Estonia	no									
France	no									
Denmark		1992								2004
Finland		1994	1993	1994						
France			2002							
Germany									1939	
Greece					2010					
Hungary									1997	
Iceland		1990	2005							2005
Ireland	no									y
Italy		y								
Latvia (physicians)					x	x				
Liechtenstein		1985								
Lithuania (physicians)					x					
Luxembourg	no									
Malta		x	x			x				
The Netherlands	no									
Norway		1988								2004
Poland	no									
Portugal		2003	2003		2003	2003	2003	x		
Spain					2009					
Slovakia	no									
Slovenia		2007	2007		2007	y				
Sweden		1989		1994						y
Switzerland		x	x						x	
UK		1994	1993		1950	y		y		x
Number	11	13	8	2	7	4	1	1	3	4

B. Teaching of homeopathy and use in hospitals in 22 European countries (5)

Austria :

Officially recognized diploma as an additional qualification (medical doctor / veterinary doctor qualified in homeopathy). Postgraduate education. Optional **introductory course** on CAM during basic education at the universities of Vienna, Innsbruck and Graz.

In 11 hospitals homeopathic care is possible on consultation.

Belgium :

Post-graduate **diploma** delivered by private schools. A National diploma exists delivered by the Homeopathic Faculty, grouping the different schools.

A compulsory optional **introductory course** at the University of Leuven (U.C.L.)

No official possibility for homeopathic care in hospitals but patient's rights include homeopathy as a possible patient choice in collaboration with the family medical doctor.

Bulgaria :

Postgraduate **diploma** in private schools recognized by the medical association.

No possibility of homeopathic care in hospitals.

Czech Republic:

Postgraduate **diploma** in private schools.

No possibility of homeopathic care in hospitals.

Denmark:

Education in private schools open for everybody (no formal medical education required)

No possibility of homeopathic care in hospitals.

Finland :

Education in private schools, open for everybody (no foregoing medical education required)

No possibility of homeopathic care in hospitals.

France :

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the universities in Aix-Marseille, Besançon, Lille, Paris-Bobigny, Bordeaux II, Limoges, Poitiers and Lyon. Private schools also exist. Optional **introductory course** of CAM during the basis education at some universities

In 2 hospitals patients can come for a homeopathic consultation: Hôpital St. Jacques en Hôpital St. Luc Paris.

Germany :

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at the universities of Berlin, Düsseldorf, Hannover, Heidelberg and Freiburg. Private schools also exist

Compulsory optional **introductory course** of CAM during the basic education at some universities

In 1 hospital patients can come for a homeopathic consultation: 'Charité' hospital in Berlin.

Greece :

Postgraduate diploma in private schools and some universities.

No possibility of homeopathic care in hospitals.

Hungary :

Postgraduate diploma in private schools recognized by the medical chamber.

No possibility for homeopathic care in hospitals.

Ireland :

Postgraduate diploma in private schools, open for everybody (no foregoing medical education required).

No possibility for homeopathic care in hospitals.

Italy :

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate courses for medical doctors in Bologna, Roma, Siena (also dentists and pharmacists) Universities.

Postgraduate diploma in private schools for medical doctors, dentists, veterinarians, pharmacists. Postgraduate diploma organized by the Provincial Medical College in Reggio Calabria.

No possibility for homeopathic care in hospitals at this moment but announced.

Luxembourg :

Postgraduate diploma in private schools.

No possibility for homeopathic care in hospitals.

Netherlands:

Postgraduate diploma in private schools.

Optional introductory course of CAM during the basis education at some universities

No possibility for homeopathic care in hospitals.

Norway :

Education in private schools, open to everybody (no foregoing medical education required).

No possibility for homeopathic care in hospitals.

Poland :

Officially recognized **diploma** as an additional qualification (medical doctor /veterinary doctor qualified in homeopathy). Post-graduate education at 8 universities. No possibility for homeopathic care in hospitals.

Portugal :

Postgraduate **diploma** in private schools.
No possibility for homeopathic care in hospitals.

Romania :

Officially recognized **diploma** as an additional qualification (medical doctor/veterinary doctor qualified in homeopathy). Post-graduate education at 8 universities. Optional **introductory course** of CAM during the basis education at some private universities
No possibility for homeopathic care in hospitals.

Slovenia :

Postgraduate education at the private school of the Slovenian Homeopathic Society accredited by ECH.
No possibility for homeopathic care in hospitals.

Spain :

Officially recognized **diploma** as an additional qualification (medical doctor/veterinary doctor qualified in homeopathy). Post-graduate education at the universities of Sevilla, Murcia and Barcelona.
Optional **introductory course** of CAM during the basis education at some universities
No possibility for homeopathic care in hospitals.

Sweden :

Education in private schools open for everybody (no foregoing medical education required).
No possibility for homeopathic care in hospitals.

Switzerland :

Postgraduate diploma in private schools. At the university of Bern education in CAM is available.
Homeopathic care only in private hospitals.

Great-Britain :

Officially recognized **diploma** as an additional qualification (medical doctor/veterinary doctor qualified in homeopathy). The official recognized "Faculty of Homeopathy" delivers the diplomas. Postgraduate education in private schools, open for everybody.

Optional **introductory course** of CAM during the basis education at some universities

In 4 hospitals homeopathic consultations are possible: London, Liverpool, Bristol and Glasgow.

Homeopathy in intensive care and emergency services:

Recent publications show the benefit of homeopathy in hospitals but also in emergency services for patients in critical state (6,7,8,9,10). The authors suggest the development of algorithms including homeopathy allowing quick and adequate responses for these patients.

The place of Homeopathy in INDIA.:

Homeopathy is available for patients in 230 hospitals (10,851 beds) and 5,836 dispensaries. Officially registered practitioners number 217,850. Two hundred sixteen colleges are teaching homeopathy. All of these activities are coordinated by the ministry (health-education-scientific research), as follows: more and more pathogenetic trials, clinical verification, efficiency and efficacy research including cost evaluation and even laboratory research in an organized and a systematic way. India is emerging as one of the strengthened infrastructures in homeopathy.

The place of CAM in the U.S.A.:

The Consortium of the Academic Health Centres (11) integrate CAM in **30 university medical centres**. As in Great Britain, the concept of "integrated" medicine predominates. All possible treatments must be offered to the patient. This attitude is based on the results of intensive scientific research on CAM. Thus far the results are very hopeful for homeopathy.

SUMMARY OF FIRST PART:

In the World, the use of homeopathy has increased in many countries. In Europe, homeopathy, as other CAM, is already partly regulated. Homeopathy is integrated in 6 of the 22 countries. Medical students get familiar with CAM by an introduction course in 9 of the 22 countries. A postgraduate diploma in homeopathy is recognized in 18 of the 22 countries. Despite the interest there are still some queries outstanding before considering full integration in all countries. Part 2 will study the reasons for this reservation.

Second part of chapter II

Arguments in relation to the reservations about CAM, in general, and homeopathy, in particular.

We know that in some European countries integration of homeopathy in the health services, even at University hospitals, is already accomplished. Nevertheless, some people resist this integration.

The conventional pharmaceutical industry, with its enormous financial power, does not like the development of "other" medical systems of medicine that could be an alternative to their market. This resistance is not really structured but competition is always a problem and if there is some opportunity to limit the action field of the "others" they will not hesitate to use it.

The "rationalists" are not so numerous but very well organized and very influential on the mass media. One single argument is sufficient to condemn everything that they do not accept: *"it is simply impossible that something would exist out of their rational way of thinking"*.

Scientific doubt is rejected. Scientific facts that do not find an explanation within their paradigm are *a priori* false. *"Somewhere there must be an error"*. This "rational world" is based on, and limited to, the molecular paradigm that is part of molecular biology. Outside of this scientific paradigm nothing can exist. However, other intercellular communication means do exist: biophotons (12), biophotons (13) and electromagnetic waves (14) have been identified; they are activated by the communications between cells and molecules. There is also the molecular print in a solvent (15). These facts are not explicable by the molecular biology. Even effects of hormones cannot be explained only by the molecular theory because the number of molecules is insufficient to explain the amount of activated cells receptors; therefore the so-called "amplification" phenomenon must be developed.

As such, the major reason for rejection of scientific research in the field of homeopathy is a theoretical reticence. Research would not be necessary because the observed effects cannot fully match the molecular paradigm

and its investigations' methods. Therefore, possible cures with homeopathy must all be due to the placebo effect associated with psychological influences (believing) and even spontaneous healing. Of course, this position forgets the results achieved on animals and in children and that a great majority of the delivered medicines are on a "molecular level". As an example of this position, we can consider a publication in *The Lancet* (16), in fact a scientific fraud (17, 18), but such publication based on manipulation of facts would be sufficient to justify the placebo theory and rejection of further research into homeopathy. By redoing this statistical exercise, it was possible to confirm the fraud and to deduce that the conclusions of this publication must have been written before looking at the facts. The authors used a new mathematic model for literature analysis that could confirm these conclusions. Unfortunately, the strict application of this new method came to a conclusion they did not desire, namely homeopathy is efficient in certain areas. The authors preferred to avoid these results and to quote only some negative results in accordance with the a priori desired conclusions. The redaction committee of *The Lancet* were very interested in the negative conclusions and the impact such publication could have in the mass media and did not scrutinize enough the content of this paper.

The Royal Academy of Medicine in Belgium recognized in 2009 that the conclusion of *The Lancet* editorial ("Homeopathy is a placebo") cannot be sustained from this publication (see further).

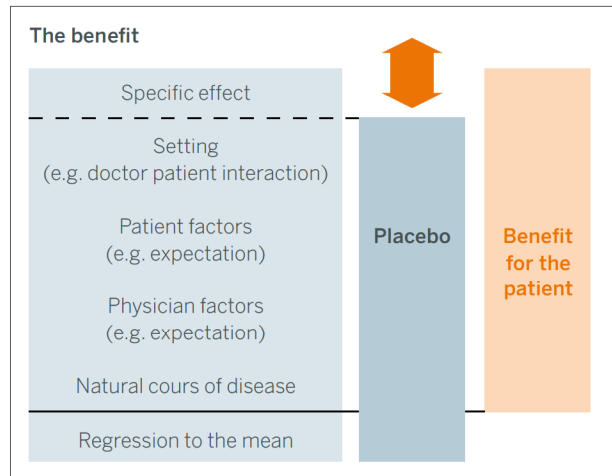
In fact, this is a war between two different paradigms. The dominant paradigm must explain everything and if something cannot be totally explained by this dominant paradigm, it will be considered as artefact. However, new paradigms exist and could explain other facts. As example, *the paradigm of information* does not "eliminate" the *molecular paradigm*, it is an additional paradigm that can explain some facts that the molecular paradigm does not explain at all.

We shall not minimize the importance of the unspecific effects in each medical approach. A placebo has been defined as "a substance or procedure ... that is objectively without specific activity for the condition being treated". Under this definition, a wide variety of things can be placebos and exhibit placebo effects. Pharmacological substances administered through any means can act as placebos, including pills, creams, inhalants, and injections. Medical devices such as ultrasound can act as placebos. Sham surgery, sham electrodes implanted in the brain and sham acupuncture, either with sham needles or on fake acupuncture points, have all exhibited placebo effects. The physician has even been called a placebo; a study found that patient recovery can be increased by words that suggest the patient "would be better in a few days", and if the patient is given treatment, that "the treatment would certainly make him better" rather than negative words such as "I am not sure that the treatment I am going to give you will have an effect." The placebo effect may be a component of pharmacological therapies: pain killing and anxiety reducing drugs that are infused secretly without an individual's knowledge are less effective than when a patient knows that he is receiving them. Likewise, the effects of stimulation from implanted electrodes in the brains of those with advanced Parkinson's disease are greater when they are aware that they are receiving this stimulation.

The placebo effect has been controversial throughout history. Notable medical organizations have endorsed it, but, in 1903, Richard Cabot concluded that it should be avoided because it is deceptive. Newman points out the "placebo paradox". – it may be unethical to use a placebo, but also unethical "*not to use something that heals.*" He suggests to solve this dilemma by appropriating the meaning response in medicine, that is make use of the placebo effect, as long as the "one administering ... is honest, open, and believes in its potential healing power." David H. Newman. *Hippocrates' Shadow*. Scribner (2008). p. 134-159. ISBN 1-4165-5153-0.

Professor Dr Claudia M. Witt (MBA. Institute for Social Medicine, Epidemiology and Health Economics/ Charité University Medical Center Berlin/ www.charite.de/cam) presented at the 63rd LMHI congress (2008), a communication on research in homeopathy. This research is

aimed at isolating the specific effects of the homeopathic medicines from the other effects of the medical approach with a patient.



The hypothesis that "the placebo effects, during placebo-controlled clinical trials of individualized homeopathy are higher than in conventional medicine" was scrutinized in a systematic literature analysis in 2010 (19). The results were that in 13 matched sets the placebo effect in homeopathic trials was larger than the average placebo effect of the conventional trials; in 12 matched sets it was lower. Additionally, no subgroup analysis yielded any significant difference. As such placebo effects in Randomized Controlled Trials on classical homeopathy did not appear larger than placebo effect in conventional medicine.

Usually common medical doctors, especially specialists, are not interested in other medical approaches and researches. They know very well what they are doing every day; they are satisfied with the results obtained in a majority of their patients and do not need something else. They are only interested in more research, information and improvement of their actual practice. If some patients are not ameliorated by, or do not tolerate the proposed treatment, they are classified as "difficult," "untreatable" patients. The therapy will not be questioned and research on other approaches will not be considered. They are not "against" homeopathy but why would they encourage better studies on a medical approach they do not know?

Third part of chapter II

Ethical aspects

The Position of Ethics

Two fundamental rights must be taken into account: *the therapeutic freedom for therapists and the freedom of choice of therapy for the patient.*

1. The bio-ethic of the 21th Century and sources:

It is good to mention some existing important ethical lines and their applications in the field of alternative medicine. If we consider the actual medical ethic, one can observe that there is a tendency to go further than the oath of Hippocrates, just because the ethic is taking into account technical and human complexity. So medical ethics is in permanent mutation and permanently questioned.

a. Appearance of the medical techno-science

In the context of the medical technology, especially in the fields of research connected with human life, the bio-ethic is concerned. Science cannot remain morally neutral.

b. The role of the concept "scientism" in the actual way of thinking:

3 important steps are distinguished by A. Comte in the evolution of a human being.

1. The theological step: humans cannot explain understandable phenomenon by religion.
2. The metaphysical step: the appearance of abstract entities.
3. The step of the positivism.

• Phenomena are connected to laws

(Constant relation among phenomena).

In the positivist attitude, science becomes the foundation of the individual and social life. The moral conscience is obliged to evolve as quickly as the evolution of the science as a consequence of this positivist attitude. The result is an ethical revolution. Trying to define the actual concept "moral," a possible approach can be in connection with his hereditary nature: the moral conscience is the result of the heritage of the human feelings (example: compassion, devotion). Thus the "moral" is the result of the sociobiological evolution we transmit. This approach of the terminology "moral" can be confirmed by the inability of the human being to make a final law about human rights. It is necessary to consider an evolving bio-ethic, based on the evolution of the nature of the human being.

• Where would we place homeopathy and CAM in this context?

Using the positivist attitude, homeopathy is based on the fact that it is a fully experimental science. But homeopathy exceeds this positivist attitude, keeping a "metaphysical" aspect. The homeopathic phenomena are only linked to the natural right.

c. Positivism.

Conventional medicine is based on scientism. It is important to underline that the representatives of this conventional science determine laws, allocations of budgets and the composition of the ethical committees. The National Ethical Committee is composed and directed by researchers who are at the same time judge and jury! Therefore we can understand that political action is based on ethical orientations submitted to the rules of the dominant science paradigm. Orientations are decided not only by a compromise among individuals but also by a social consensus. The actual ethic is indeed accepted by the majority of the people but it is not based on the individual rights of every human being. In this way it is immediately submitted to legislative power.

The actual ethic is based on 2 principles:

- 1) **Difference between *the ethic of conviction and the ethic of responsibility*** (Theory of Weber)
- 2) **Discussions as empirical tool to come to a consensus.**

The ethic of conviction is based on the principles of the metaphysics and of religion.

On the other hand, the ethic of responsibility disregards these principles. The ethic of responsibility is more adapted to a rational approach of the problems caused by the progress of the medical research. When formulating a law, a consensus can be reached by discussion. Society confirms the accepted laws. These laws are the result of a dialogue based on the expression of all opinions above all convictions. References to "truths" or to the "absolute" must be avoided because interaction would not be possible anymore. It may become clear that the moralistic philosophy and the positive right have different subjects and methods. The positive right covers the practice, protects persons and punishes infringements; at this level a minimal consensus will be sufficient.

d. Access to the metaphysical dimension of the human being

This allows the describing of the limits of positivism. Therefore it is necessary to look at the relation between the positive and the metaphysical sciences. Agnosticism and Progress ideology (amelioration of mankind and well-being) dominate our actual society.

- A human being is unique and sensitive;
- A duality in science could exist: science can explain the universe but who explains science?
- Certainly there is a relation between science and spirit.

Positive sciences should only be an instrument. A human being uses this instrument, but should not be enslaved to it. Natural sciences show us how deeply we are anchored to the very depths of nature. These sciences teach us to know our impact and our responsibility to nature; a human being creates science but goes beyond this science by his spirit.

This last approach may be considered as individualistic and keeps no account with the social responsibility that is, as we have already seen, totally different. Must we accept to go on with the split between the social and individual ethic?

Because of the evolution of quantum physics, we know that homeopathy and the other CAM are not considered science in the way that the other sciences are. In this connection we have an ethical problem. The individual approach dominates in homeopathy but the social responsibility of the medical doctor homeopath is the same as of every other medical doctor.

2. The bio-ethic and its most important currents

The most common definition of the bio-ethic could be formulated as following "*science of morals*." This definition is confusing because the reason for the existence of ethics is not scientific. All bio-ethical problems such as research on embryos and euthanasia divide our conscience. These problems also penetrate the field of contemporary homeopathy.

Let us reflect on the origin of the word "ethic," originating from the Greek word "ethos" ("*safe home*"). Referring to this source, one finds that ethics is neither a matter of arguments, nor of concepts. Ethics is more a state of mind, a way of being in the presence of the pain appearing on the face of another. Emmanuel Levinas defines pain as "*the impossibility of finding a safe home*". So, it should be logical to consider ethical all actions done with the expectation to make the world more liveable. Homeopathic medicine and CAM, like the whole humanistic world, is par excellence a medicine of hospitality, listening to the patient with the purpose of enlightenment of the pain by offering him a new "safe home".

It is interesting, in accordance with the discussions going on at this moment at the international level about the factor "health", to explain two dominant ethical sensitivities:

- The first one is the "*utilitarian ethic*" predominant in the Anglo- Saxon world.
- The second one is the "*deontological*" inspired more from the continental way of thinking.

We will place homeopathy and other CAM therapies in relation to the problems encountered concerning the national diversity of the concept of philosophy.

A. The utilitarian Ethic

The emphasis is put on the “utility” of each action for “the highest happiness for the most possible number of people.” The utilitarian concept evaluates the moral value of an action to its consequences (not the intentions, but the consequences count). The founder (Bentham) of the utilitarian ethic said: *“good is what is good for me without harming the other”*. The utilitarian ethic is also called *“naturalistic”*: namely, acting according to good is acting respectful of the gifts of nature to us.

It is a philosophy proclaiming the “doctrine of enjoyment” and, as such, including the free transactions between persons under the form of a contract. The problem of a woman carrying a child for another woman or of the selling of cosmetics is illustrative: why forbid when everybody enjoys it?

B. The Ethic of the Deontology

The deontological ethic (“Deon”= Greek = what is necessary to do) is not based on the right of enjoyment but on the duty to be respectful of the other person. Here one could say that it is a *“person-bound”* ethic. Kant is the symbolic person for this movement. Not only are the consequences of an action important but also the intentions preceding our behaviour. *“Act in a way you should treat humanity as well as you would yourself and the other; always and at the same time as an aim and never only as a tool.”* We cannot accept a world where people consider their body as a business.

C. Applications to Homeopathy

Homeopathy was the object of so much scepticism in the 20th century. This is mainly because of the fact that it is integrating science and “non scientific” knowledge. They seem to leave the framework of the positivist medicine. To integrate homeopathy in our health service, they have to be in harmony on the ethical level. Ethical questions, typical for complementary and alternative medicine must be considered. What is needed to integrate them safely into the existing health system, offering patients and medical doctors a free choice of therapy?

a. Developing at European Union level, and in the world, legislation allowing the integration of CAM in the health services.

The integration of the practice of CAM and homeopathy in free medical practice and in the structures of hospitals is necessary. It is a matter of social and ethical good

sense. For medical doctors, the social and collective responsibility is also linked to their deontological responsibility. By integration, it will be ethically possible to offer patients more medical approaches respecting freedom of choice even when s/he moves from one country to another.

b. CAM therapies have their own fields of action and indications and are not allowed to replace the conventional medicine with its specific indications.

It is necessary to define the indications for CAM; homeopathy and some CAM therapies are curative in certain clinical situations. In some pathology, scientific studies showed positive results. On the other hand, their application may not be indicated in other specific situations and modern technology would be preferred in order to help the patient.

c. Problems related to life.

A medical doctor will be consulted regularly for problems related to “life”. The medical doctor, having at his/her disposal complementary and alternative therapies, is more able to advise the patient about a medicine respecting natural rights. His advice can be an element for discussion in regard to a heavy technical intervention. On the other hand there must be a deontological ethic to this advice evaluating also what may be the consequence of this decision for the well being of the patient.

d. The freedom of choice for the patient as well for the physician.

This is a fundamental right, based on clear and unbiased information that a medical doctor can give to a patient. At this level, the education of a medical doctor in conventional as well as in alternative medicine is necessary. After a medical diagnosis it will be possible, for this medical doctor, to offer his patient different possible available treatments. The patient can make his/her choice when s/he is well informed. When the physician has to make this choice, he has to consider all ethical aspects as well as the methods he considers using for treatment.

e. Homeopathic medicines.

Homeopathic medicines have very precise indications. Their action is proved by research and validated clinical trials (see further). Homeopathy is an experimental science, based on clinical research and verification. On the other hand, research gets only little support at the national level as well as the European or intercontinental authorities. CAM and especially homeopathy ask for validation and financial support by the authorised authorities so that from an ethical point of view the user of these products can get guarantees about safety and efficacy.

IN CONCLUSION:

Looking towards a more humanistic medicine, in contrast with a very technically and over specialized medicine, the reconciliation between scientific progress and respect for the human person must be a priority.

Therapies such as homeopathy have several indications in the field of chronic as well as in the field of acute diseases; even within very extreme situations (comatose patients). We may see in intensive care units that homeopathy can help patients.

For the wellbeing of everybody, the development of research within homeopathy is necessary; funding it, in a correct way, is needed as is a good education in Medicine and in homeopathy for the physicians using homeopathy.

The patient becomes impatient.

When everything is regulated, a free choice for the patient and the medical doctor will be possible. Efficient results and the amelioration of a patient's health and welfare will be guaranteed.

CHAPTER III

Framework of the practice: Belgium (Europe) as an example.

Survey IPSOS, May 2011, on a representative sample of the Belgian population above 18 years old (1000 = 100 %); 21.7 % do not know homeopathy at all; 78.3 % are aware of the existence of homeopathy in Belgium; from them 38.8% never use homeopathy but 11.8 % are open for this use if needed; 39.5 % are (or were 5.1 %) using homeopathy. In the users group, 55 % are users for more than 5 years, 17 % between 3 and 5 years, 7 % between 1 and 2 years, 4 % for some months and 17 % do not know.

	Recent problems in the family	Use of homeopathy
Winter events (coryza, cough, otitis, influenza, etc.)	20 %	++++
Pain in joints	16 %	++
Allergy	10 %	+++
Stress	8 %	++
Injuries	7 %	+++
Hypertension	7 %	
Bowel problems	6 %	++
Prevention (Influenza, allergy, etc.)	4 %	++
Skin symptoms (Eczema, etc.)	3 %	+
Diabetes	3 %	
Heat flushes	3 %	+
Urinary infection	2 %	
Teething problems (child)	1 %	+
None of these	10 %	
	Together 100 %	Users 40 %

Motivations for using homeopathy: better for health 57 %; avoiding "chemicals" 41 %, efficacy 39 %, medical doctor prescription 32 %, advice of a friend 28 %, advice of the pharmacist 23 %.

Motivations for non-users: 43 % do not know homeopathy well, not proposed by my medical doctor 40 %, not proven 30%, slowness of action 30 %, I am not ill 28 %, I do not know an homeopathic doctor 25 %.

The most important channels for the use of homeopathy are the family doctor (84 %) and the pharmacist (66 %). Information about homeopathy is expected from the medical doctor (58 %); from the pharmacist (39 %); from the internet (36 %); from the media (29 %) and from books (15 %).

More than 22 % of the family doctors prescribe homeopathic medication more or less on a regular basis. Three percent of them prescribe homeopathy as a first choice.

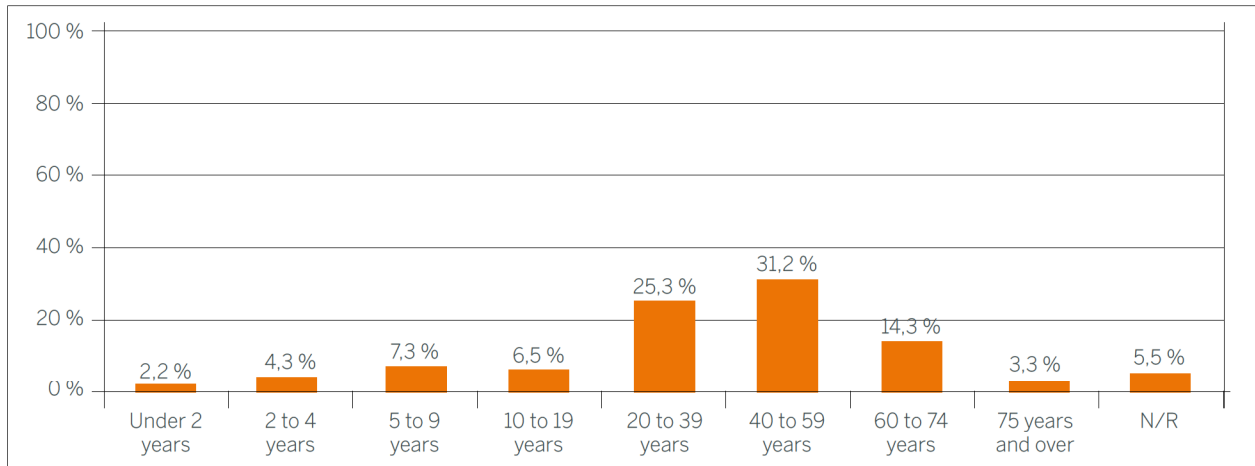
The profile of the medical doctor homeopaths, members of a Union shows that a majority (87 %) are first line Medical Doctors. There is also a broad use of homeopathy by veterinarians and dentists. Pharmacists are more and more longing for knowledge on homeopathic preparation and how to offer advice about homeopathy.

The reasons why patients ask for a homeopathic treatment are various and are certainly not limited to "easy to cure" indications.

From an earlier publication (20): Inquiry of 6000 persons, representative of the Belgium population, homeopathy is used for grave and chronic illness (17 %), 17 % for specific diseases like allergic conditions, 7 % due to inefficacy of conventional treatments and 3 % because intolerance to some conventional drugs.

Although all ages are represented, from pediatrics to adults, 75+, but the group above 55+ years old is considered to be the most expensive for the budget of the National Health Service.

3.1.2 Age group overall



The demand and supply of the medication in the pharmacy was also scrutinized in the same inquiry. Self-medication covers 15 % of the demand; the physicians (prescriptions) are responsible for 44 % and the pharmacists' advice covers 30 %.

One may conclude that the use of homeopathic medication is widespread (even more than expected including self medication and pharmacists' advice).

Within the framework of the complementary insurance, reimbursement of prescribed homeopathic medicinal products is possible from 25 % to 50 % of the price.

Several inquiries on medical doctor homeopaths show that most of them prescribe homeopathy within the framework of first line medicine.

Every MD receives, yearly, his individual profile of prescriptions of **medical imaging** and **clinical biology** from the National Institute of Health. This profile allows us to make a comparison between the profile of MD homeopaths and all other physicians.

Fifty-two percent of the accredited GP homeopaths sent their profile, the values of the consecutive years were put together and a yearly average calculated.

The year average of patient contacts was 2.415. Thirty-four percent of the Belgium physicians have fewer consultations; 66 % have more consultations.

If we consider the average amount paid back by the insurance for each individual patient contact concerning **medical imaging**, the value for this group is 2.6 meaning that only 26 % of the Belgian physicians cost less.

Seventy-four percent of the physicians cost more than the group of homeopathic physicians.

If we consider the total amount of yearly prescriptions of **clinical biology**, of MD homeopaths the worth is 2.9 meaning that 29 % of the Belgian physicians prescribe less; 71 % prescribe more. The average number of requested analyses for each prescription is higher under the MD homeopaths in comparison to the average of Belgian physicians (worth 3.7). MD homeopaths are prescribing more complete biological evaluation than the non-homeopaths MDs but in a lower frequency. This means that concerning **the total amount of demanded medical analyses**, 37 % of the physicians prescribe less than the MD homeopaths, 63 % more.

If we consider **the average amount paid back by the insurance on each individual patient contact** (if we should have the same number of yearly consultations) concerning **clinical biology** the value by patient contact is 4.8 meaning that 48 % of the Belgium physicians cost less; 52 %, more.

This confirms that the specific medical act of the homeopathic physicians creates no particular problems for social insurance. **If the costs of the clinical biology are added to the costs of the consultations the total amount for the homeopathic group situates itself at the value of 3.3 meaning that 33 % of the Belgian physicians cost less; 67 % cost more to the national insurance service.**

More information would be needed about the profile of the patients consulting a homeopathic physician in comparison with the profile of patients consulting conventional physicians. If the practice of a homeopathic physician

were completely different from the conventional one, an extrapolation could indeed have been biased. The same problem exists if the patients consult also, on a regular basis, conventional physicians for supplementary analysis. In fact, we are already sure that that is not the case; 50 % of patients are asking for a Global Medical File (inscription) by an MD homeopath.

CONCLUSIONS:

- **The practice of homeopathic doctors is part of the framework of medical practice.** Clinical biology and medical imaging are used when necessary.
- **No abnormalities are found concerning insufficient or exaggerated prescription profiles.** The profiles of MD homeopaths are similar in comparison with the conventional colleagues.
- **No significant difference in the prescriptions of clinical biology and medical imaging** prescribed by MD homeopaths in comparison with the conventional colleagues.
- The **biological analyses** of the homeopathic physician are **more complete and extensive**.

Comparison of the prescription of medicines costs at each consultation.

For GPs the cost of the prescription at each consultation is about **27 €**.

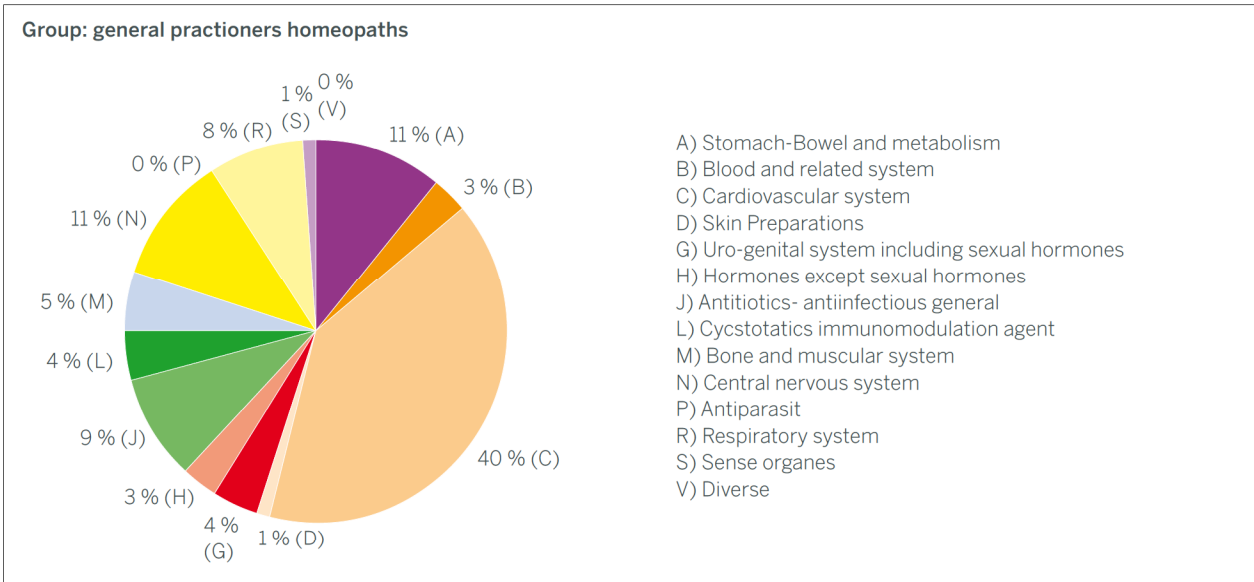
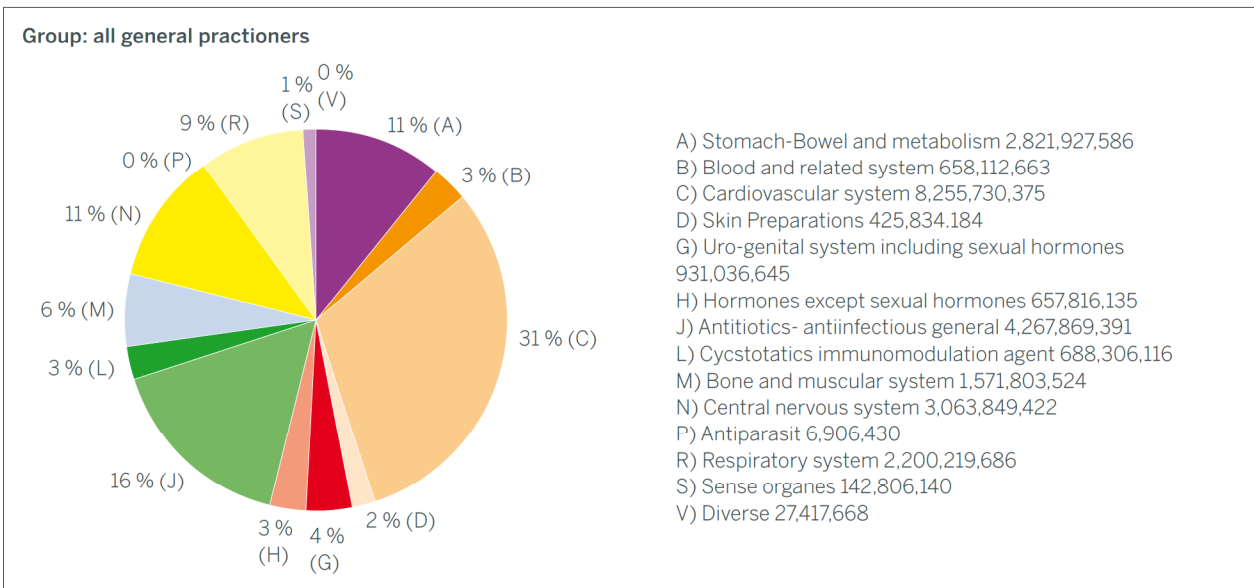
GP homeopaths prescribe, at each consultation, conventional medication for about **12 €**.

The number of patient contacts of MD homeopaths is based on the reimbursed consultations by the National Institute of Insurance Service (INAMI). A lot of patients are insured through private insurance companies and as such are not counted as patient contact, but the supply of medicines is counted. Therefore, the real number for consultations is higher and the real cost for each consultation must be corrected to **9.85 €** per patient contact. Some could say that this difference exists because the homeopathic medical doctor treats less severe ailments, but, we saw before that a homeopathic doctor treats chronic and severe diseases. This fact can be confirmed by studying the volume of prescriptions at each consultation. In this case, we can see that this volume is 50% lower for the homeopathic M.D. compared to conventional doctors.

Comparison between medicinal products.

The two following tables show clearly that the homeopathic physicians prescribe relatively more conventional remedies linked to blood and cardio-vascular problems in comparison with all medical GP's.

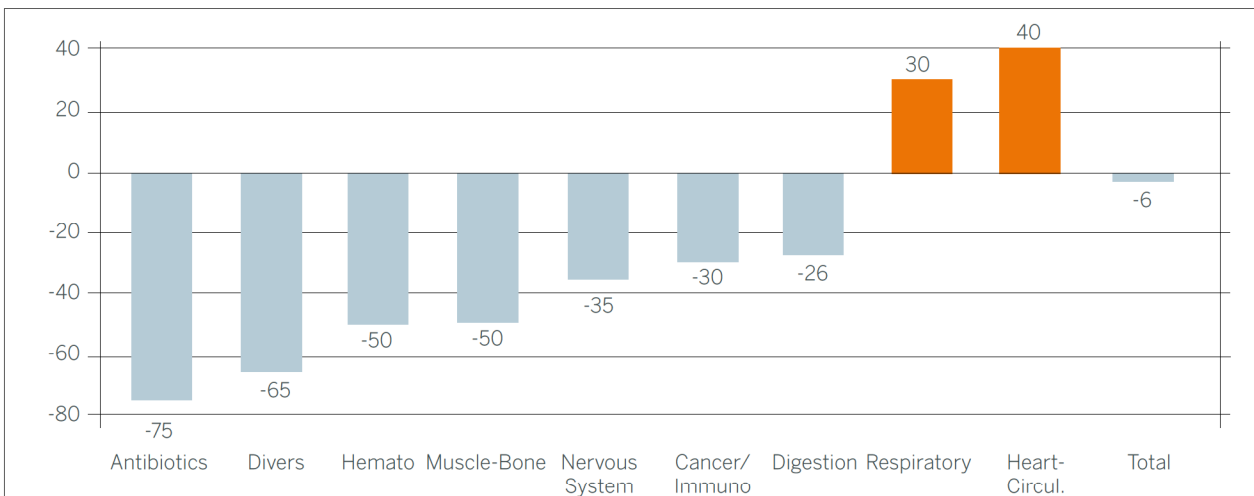
On the other hand, MD homeopaths prescribe less in other sectors, such as NSAID and antibiotics. Here a difference of 50 % is remarkable.



A homeopathic doctor sees more patients with respiratory tract problems than do conventional colleagues.

This is not the case for cardio-vascular problems where no homeopathic alternative exists.

% of prescriptions homeopaths MDs versus non-homeopaths MDs.



Conclusion of these surveys:

- The medical activity of the GP homeopath is done within **the framework of medicine**. The Royal Academy of Medicine in Belgium concluded that only when applied in this context, by qualified Medical Doctors, is homeopathy acceptable (see further).
- Prescriptions of conventional remedies occur when necessary.
- The **number of patient contacts** is **24 %** lower for MD homeopaths in comparison with all GPs.
- The **cost of each prescription** of GP homeopaths for conventional remedies is **50 %** lower (more or less 15 €)
- For hormonal treatments, uro genital and **cardio-vascular pathologies**, homeopathy may be not an alternative for the conventional treatment.
- On the other hand, there is **a spectacular decrease in percentage of prescriptions of NSAIDs and antibiotics**. This is very important for health care in general because it reduces the risk of resistance against antibiotics and subsequent iatrogenic disease through NSAIDs (stomach ulcers).
- All together, knowledge and use of homeopathy can generate a considerable decrease of the volume and of the cost of the prescriptions at each patient contact (especially for antibiotics and NSAIDs)

Of course this survey does not allow evaluation of the cost of homeopathic medicine because these data are not taken into account by the National Institute of Insurance Service (INAMI). It would be interesting to analyse the number of contacts, by a single patient, with a conventional GP in addition to the contacts with a MD homeopath when it exists.

The average amount of contacts for each patient is 5 per year to a GP homeopath.

The strategy of a treatment (only conventional or only homeopathy or both) depends on the diagnosis. Homeopathic therapy is only possible within the framework of medical practice taking into account the freedom of therapy for the medical doctor.

All these results are published (20) and some more facts are of interest, as follows:

The treatment by a homeopathic physician causes an important reduction in the consultations with another GP or a specialist (2/3 less). The patients in the worst physical condition at the start of the treatment derive the most benefit from homeopathic treatment. The average length of a homeopathic consultation is 37 minutes.

As a result of a homeopathic treatment, 52 % of the patients are able to stop one or more conventional medicines. Particularly medicines for the central nervous system can be consequently reduced (21 %), along with medicines concerning the respiratory tract (16 %), and antibiotics (16 %). The homeopathic physician prescribes only 1/3 of the total amount of medicines prescribed by a conventional physician. For antibiotics, this is even only 1/5. If we extrapolate this to all patients, this would give a reduction of 2/3 on the budget of medicines.

Through all these surveys we showed that homeopathy has a place and has to stay or be implemented at least within the general practice of first line medicine. There is no evidence of any medical deviant conduct by the homeopathic physician.

At the 63rd LMHI congress (May 2008) comparable results were presented for France, Italy and USA:

- Chaufferin G. L'homéopathie est-elle coût-efficace ? Homeopathic medicines represent 6 % of distributed medicines but only 1 % of the costs in medicines for the patients.
- Rocco V, Huck S, Rodriguez AA. Measuring private homeopathic practice in Italy. An important factor in the decision to come to homeopathy is MDs competence, education and experience.
- Frye J. Comparing use of homeopathy with a practitioner and use as self-care in the U.S. 2002 National Health interview survey.

For more general information see Bornhöft G, Matthiessen P. **"Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs."** Berlin: Springer, 2011
www.springer.com/medicine/complementary+%26+alternative+medicine/book/978-3-642-20637-5

CHAPTER IV

META ANALYSES – SYSTEMATIC REVIEW

The “gold standard”, accepted by everybody to evaluate the efficacy of a remedy is a meta-analysis or a systematic audit of RCTs. Since 1991, six comprehensive reviews concerning homeopathy were published.

The conclusion of most comprehensive systematic reviews has been that homeopathy has a positive and

specific effect greater than placebo alone. Several randomized and controlled studies (RCT) showed a statistical significance difference between homeopathy and placebo. More research is justified.

Report about all comprehensive systematic reviews on homeopathic trials

- **Kleijnen & al. 1991** (21) *British Medical Journal*. 105 studies with interpretable results. Meta-analysis based on validated criteria.
 - 77 % of the studies show positive result for homeopathy.
 - The results are mostly favourable for homeopathy regarding the quality of trials.
 - “There is a legal argument for further evaluation of homeopathy”.
- **Boissel & al. 1996** (22) *Report for the European commission*. 15 studies. Inclusion of only very rigorous studies (highest quality).
 - Combined p-values for the 15 studies is significant. ($p = 0.0002$).
 - “It is evident that homeopathy is more efficient than placebo”.
 - Little evidence for non-published negative results.
 - Further research is justified.
- **Linde & al. 1997** (23) *The Lancet*. 89 studies.
 - “Odds ratio” combined 2.45 (95 % CI, 2.05-2.93) in favour of homeopathy.
 - “Odds ratio” for the best 26 studies was 1.66.
 - It is not possible that the clinical effects of homeopathy are due completely to placebo.
- **Linde and Melchart 1998** (24) *Journal of Alternative and Complementary Medicine*. 32 studies, inclusion of studies on individualised homeopathy only (22).
 - Individualised homeopathy is more efficient than a placebo: the value of the combined coefficient was 1.62 (95 % CI, 1.17-2.23).
 - Further pragmatic research is justified.
- **Cucherat & al. 2000** (25) *European Journal of Clinical Pharmacology*. 16 trials representing 17 comparisons with placebo (based on data from the Boissel 1996 study).
 - Several studies have positive results. More trials have a positive result than would be expected to chance alone.
 - Publication bias is unlikely.
 - More clinical trials are needed.
- **Shang & al. 2005** (26) *Lancet*. 110 trials included, but the final conclusion is based on a selection of 8 trials.
 - Final conclusion (8 heterogeneous trials) : weak evidence for a specific effect of homeopathic remedies, but strong evidence for specific effects of conventional interventions
 - Presented as comparison of homeopathy and carefully matched conventional trials, but data about conclusive trials were missing
 - Quality of homeopathy trials is better: 21 (19 %) good quality trials for homeopathy, 9 (8 %) for conventional medicine.
 - Homeopathy is effective for acute upper respiratory tract infections (odds ratio 0.36 [95 % CI 0.26–0.50]), based on 8 trials without indications for bias.

Comments on meta-analyses

Randomized Controlled Trials (RCTs) for homeopathy were originally meant to prove that homeopathy as **a method is** not a placebo effect, despite the questioned mechanism of action. For this purpose meta-analyses combined trials for different indications in one analysis. Despite heterogeneity that arises from such combinations, some positive evidence could be demonstrated in a number of meta-analysis. We would like to stress that these analyses disregard the surplus value of homeopathy. Homeopathy is predominantly used by patients with chronic and recurrent complaints and is valued for the fact that it appears to have systemic effects, exceeding single indications as is common in conventional medicine.

Selecting subgroups in a limited number of trials readily leads to false negative results. *The Cochrane Handbook for Systematic Reviews* states "Reliable conclusions can only be drawn from analyses that are truly pre-specified before inspecting the trials' results" (28). *The Cochrane Handbook* further recommends, "Meta-analysis should only be considered when a group of trials is sufficiently homogeneous in terms of participants, interventions and outcomes to provide a meaningful summary". Pooling of results of studies on different conditions is also questionable if homeopathy works for some conditions and not for others (29). Because of the questioned mechanism of action the evidence for homeopathy was scrutinized in a way that is not required for conventional therapies. Linde et al (1997) showed that the positive outcome for homeopathy cannot be explained by publication bias (23). Shang et al (2005) showed that quality of homeopathy trials is better compared to conventional trials matched on indication (26).

The analysis by Shang, et al., (2005). This analysis did not comply with the QUOROM guidelines that sufficient information should be given to reconstruct the conclusions. The authors did not reveal which trials (8 for homeopathy, 6 for conventional medicine) led to the final conclusion. Neither the summary nor the introduction clearly specified the aim of the study. The meta-analysis does not compare studies of homeopathy versus studies of conventional medicine, but rather specific effects of these two methods in separate analyses (30, 31, 32, 33). Therefore, a direct comparison must not be made from this study. Post-publication data revealed that the conclusion was not based on a comparison with matched conventional trials, as suggested by the authors (34). The conclusion was based on 8 studies for 8 different indications; the inefficacy of one of these indications, muscle soreness in marathon runners, was already proven (35).

The conclusive subset of 8 trials was based on a *post hoc* definition for 'larger trials', n=98 for homeopathy and 146 for conventional medicine. If 'larger' would have been defined as 'above median sample size', including 14 homeopathy trials, the outcome would be significantly positive. Excluding the indication 'muscle soreness in marathon runners' homeopathy is efficacious in most subsets of larger good quality studies.

Shang, *et al.*, stated that the asymmetry of the funnel plot indicated inefficacy when compared with conventional medicine. This comparison was not rectified because of difference in quality, especially in smaller trials. For trials with sample size <100 homeopathy had 14 good quality trials and conventional medicine 2 ($p=0.003$). Stronger effect in smaller good quality trials is caused by better selection of patients and then asymmetry of the funnel plot is no indication for bias. Funnel plots are thought to detect publication bias, and heterogeneity to detect fundamental differences among studies. New evidence suggests that both of these common beliefs are badly flawed. Using 198 published meta-analyses, Tang and Liu demonstrate that the shape of a funnel plot is largely determined by the arbitrary choice of the method to construct the plot (36). When a different definition of precision and/or effect measure was used, the conclusion about the shape of the plot was altered in 37 (86 %) of the 43 meta-analyses with an asymmetrical plot suggesting selection bias.

As stated before, Shang, et al., were not clear about the aim of their analysis. The methodology of comparing homeopathy with conventional trials matched on indication was suited for comparison of quality. Comparing of effects of subgroups was not allowed because the matching was lost in forming subgroups. *The only valid conclusion of this analysis is that quality of homeopathy trials is better than of conventional trials, for all trials ($p=0.03$), but also for smaller trials with $n<100$ ($p=0.003$).*

Another interesting finding from Shang, *et al.*, data was: "The eight trials of homeopathic remedies in acute infections of the upper respiratory tract that were included in our sample, the pooled effect indicated a substantial beneficial effect (odds ratio 0.36 [95 % CI 0.26–0.50]) and there was neither convincing evidence of funnel-plot asymmetry nor evidence that the effect differed between the trial classified as of higher reported quality and the remaining trials". In 1997, Linde stated that, "homeopathy functioned not better than placebo in a specific disease". Thus the original hypothesis that homeopathy as a method is a placebo effect was reformulated towards specific

indications. This hypothesis corresponds with systematic conventional research. The advantage is less heterogeneity in the set of analyzed trials, but it disregards the surplus value of homeopathy, see above (27). Compare this surplus value with psychotherapy and Post Traumatic Stress Disorder (PTSD) with symptoms like palpitations, flashbacks, headache and insomnia. Psychotherapy gets closer to the source of the disease than a combination of beta-blockers, painkillers and tranquillizers. It would make no sense to require RCT evidence that psychotherapy works better than beta-blockers. Likewise the same homeopathic medicine could cure headache, eczema and herpes lips in the same patient. The real problem with homeopathy was the implausibility. It makes no sense to prove that homeopathy is plausible for one indication, but not for another.

Nevertheless, there are a number of medical conditions with proof for homeopathy: this is a solution to the problem of heterogeneity of medical conditions. Seventeen systematic reviews or meta-analyses focused on RCTs of homeopathy in 15 specific areas were performed: anxiety, childhood diarrhea, chronic asthma, delayed-onset, muscle soreness, dementia, depression, headache and migraine, HIV/AIDS, induction of labor, influenza treatment and prevention, osteoarthritis, post-operative ileus, seasonal allergic rhinitis (hay fever) and vertigo.

This critical approach has been explained by Jonas, Kaptchuk and Linde in 2003 (29). The **level I of evi-**

dence is reached for childhood diarrhea and seasonal allergic rhinitis. Other meta-analysis showed this same level for allergic rhinitis (37), post-operative ileus (38), rheumatoid arthritis (39) and the protection from toxic substances (40).

Level IIa of evidence is obtained for asthma (41), fibrositis (42), influenza (43), muscular pain (44), otitis media (45), several pain sensations (46), side effects of radiotherapy (47), strains (48) and infections of the ear, nose and throat (49).

Level IIb of evidence is obtained in the treatment of anxiety (50), hyperactivity disorders (51, 52), irritable bowel (53), migraine (54), osteoarthritis of the knee (55), premenstrual syndrome (56), pain associated with unwanted post partum lactation (57), prevention of nausea and vomiting during chemotherapy (58), septicemia (59), post-tonsillectomy analgesia (60) and aphthous ulcers (61).

The practical choice of a treatment for a specific patient is only little helped by the RCT results; they are obtained in "an ideal artificial situation" far from the personal context of the patient. The homeopathic diagnosis is more than a search to a disease; it is an approach including the whole person, with the aim of an individualized and global treatment. The method of evaluation has to be adapted to this reality; today Bayes' statistics authorize such research (see further).

Advice of the Belgian Royal Academy of Medicine concerning conclusions of “The Lancet” publication of Shang-Egger (62)

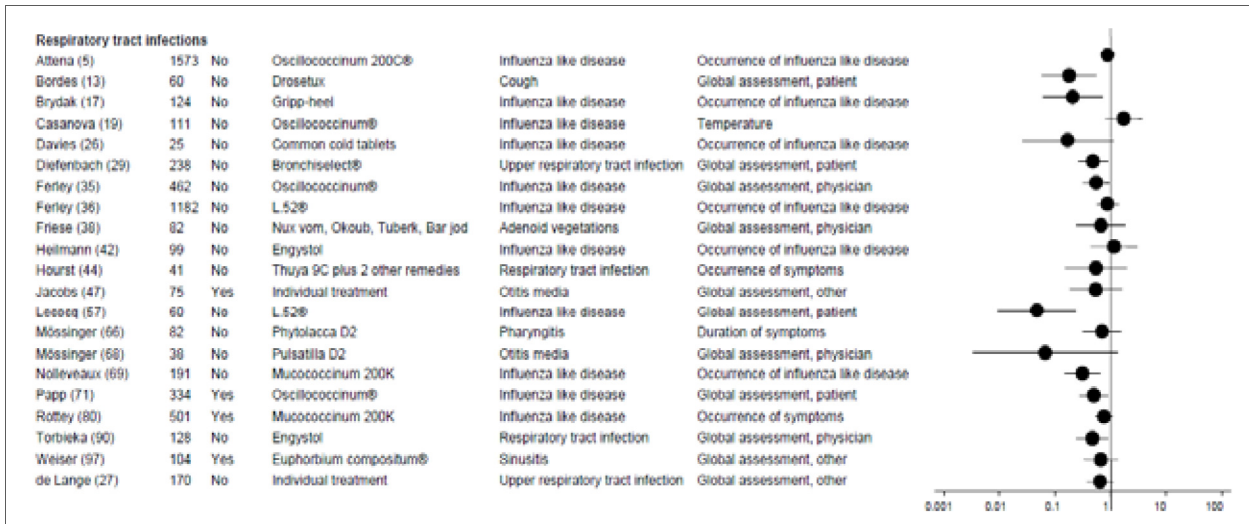
The best and most detailed critic of the Shang, et al., publication is a sensitivity analysis of obtained results and conclusions from the selected clinical trials in the final evaluation (63). If we consider the 21 trials of good quality, OR became 0.76 with IC 95% of 0.59-0.99 and $p=0.039$, argument for a homeopathic efficacy significantly higher than the placebo effect. Looking at the sensitivity of this analysis, it appears that OR is significantly different of 1 for all combinations between 14 trials ($n = \text{threshold } 69$) and the whole 21 trials (exception: the combination of 17 trials with $n = \text{threshold } 50$). However, in most of these analyses, the funnel plot reveals a moderate (but non significant) asymmetry (64). The results of predicted OR values using the technique of meta-regression (normally preferred in case of significant asymmetry) show values near one, indicating a possible absence of significant difference between homeopathy and placebo. In addition, this complementary analysis of the Shang publication reveals an important heterogeneity between the clinical trials (higher than 50 %, criteria making a meta-analyze null and void). In this case it is recommended to use the technique of meta-regression, see above, instead of a meta-analysis for traditional random purpose (65). This heterogeneity can have multiple reasons. One of these is probably the kind of considered diseases or conditions. A justified reproach can be done to Shang in the fact that he retained in his analysis trials where homeopathy has no demonstrated effect as “muscle soreness”, particularly when one of the trial finally retained by Shang contribute to increase considerably the heterogeneity of the sample. If this “muscle soreness” trial is omitted in the analysis, OR calculated on 7 trials (instead of 8) goes to 0.88/0.80 (even if this is still not significant: IC 0.61-1.05). However, in a sensitive analysis, the difference became significant if we consider 8 trials (rejecting muscle soreness, incorporating another trial on 80 people (OR = 0.75 IC 0.58-0.96 $p=0.025$) or 6 trials with inclusion criteria of 100 people

(OR = 0.73 IC 0.59-0.91 $p=0.005$) instead of the 8 trials selected by Shang (inclusion criteria 98 people). Conversely, the positive results with the 21 trials are mostly related to the presence of two large trials on influenza. If one of these two trials would be rejected, OR is no more significantly different of one. Another consequence of this important heterogeneity is the interpretation that can be done to the funnel plot aimed to exclude small sized trials (64). Indeed, rather than considering small sized trials as more bias sensitive (and as such eliminated for the final analysis), one alternative could be to consider these small sized trials as more effective because they are performed in condition where the effect of homeopathy is particularly clear and as such an important cohort of people is not needed to demonstrate this effect (63). If this is the case (and this situation cannot be excluded *a priori*), it is clear that the exclusion of small sized trials as Shang decided, is a major bias in the final conclusion. The sensitive analysis demonstrates clearly that the significance of the observed superiority effect of homeopathy compared to placebo depends, in a crucial way, on the number of trials taken into account in the analysis.

All published meta-analyses of controlled clinical trials in homeopathy are, more or less, subjects for critics and are controversial (66). Admittedly the Shang, et al., analysis, published in the Lancet is **very critical and cannot, as such, and, with it only, support the proposed final conclusion**: *“This finding is compatible with the notion that the clinical effects of homeopathy are placebo effects.”* (67). Nevertheless, the sensitive analysis of Lütke et al., (63) is clear enough by concluding: *“Our results do neither prove that homeopathic medicines are superior to placebo nor do they prove the opposite”*.

But there is more, if we compare the matched conventional and homeopathic RCT's proposed by Shang (26) and considering only the most common reason for using

homeopathy (see Chapter III: the upper respiratory tract infections) we can see that the efficacy of homeopathy is at least equal to the conventional treatments' efficacy.

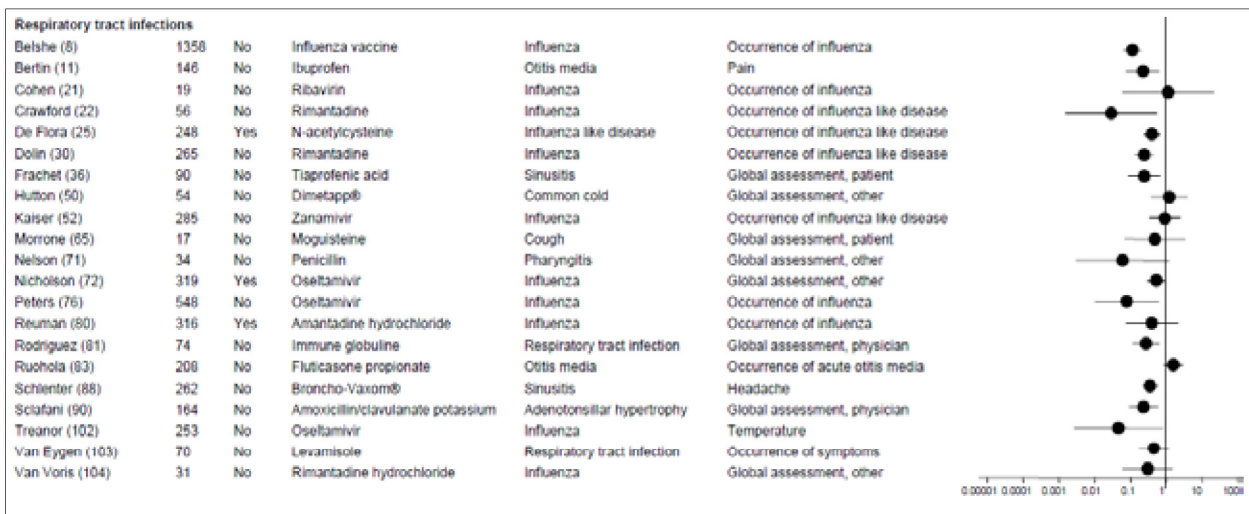


For homeopathy, 9 out of 21 publications showed statistically significant positive results, 2 negative, 4 were of high quality.

For the conventional approaches, 11 out of 21 showed statistically significant positive results, 3 negative, 3 were of high quality.

Source: www.ispm.ch/fileadmin/doc_download/1431.Study_characteristics_of_homeopathy_studies_corrected.pdf

Source: www.ispm.ch/fileadmin/doc_download/1431.Study_characteristics_of_allopathy_studies_corrected.pdf



Coming to the point, it is relevant to quote the conclusions of R.T. Mathie published in the journal *Homeopathy* (Vol 92, Issue 2, April 2003, Pages 84-91) after a review of the available literature he concluded: *“The available research evidence emphasizes the need for much more and better-directed research in homeopathy. A fresh agenda of enquiry should consider beyond (but include) the placebo-controlled trial. Each study should adopt research methods and outcome measurements linked to a question addressing the clinical significance of homeopathy’s effects.”*

Prospective comparison surveys between medical approaches would be promoted (non-inferiority trials) in specific areas described further in this booklet. Randomized placebo-controlled trials are of course a reference for “the best evidence” but respect of the individualized homeopathic treatment and daily practice must always be considered (a very difficult point considering the individual approach in homeopathy).

As such, we could conclude that more research is certainly needed considering the coherent beam of available results in specific areas described further in this booklet. All levels of evidence are needed.

CHAPTER V

THE RESULTS OF THE 'ECHO'-STUDIES

'ECHO' refers to surveys looking at Economic, Clinical and Humanistic Outcomes.

In the literature 21 publications, using validated scores concerning quality of live (QoL), are found to evaluate the efficacy of homeopathic medicines. Twenty thousand and five patients are included in the different studies. A **level IIIa of evidence** is obtained for all ECHO-studies (all diagnoses merged).

A first group of studies compares the QoL score before and after the treatment. The control group is the group itself before treatment. The improvements are statistically and clinically significant, for all merged diagnoses. Some diagnoses were considered separately: asthma in children, headache, cancer patients, anxiety and depression after stopping the estrogenic hormonal treatment because of breast cancer, allergies, general problems, intestinal disorders, anxiety disorder, depression and skin problems. These are also the most common diagnoses in general practice.

A second group uses an external control group treated with conventional medicine. The results of these studies show that the homeopathic treatment is just as efficient as conventional medicine in general practice. Respiratory problems, diabetic polyneuropathy, chronic problems in the ear, nose and throat area, e.g. sinusitis, are considered, as well as problems during pregnancy.

A third group uses the score of quality of life during a controlled and randomized study. For vertigo, homeopathy is just as efficient as conventional medicine. In a study on asthma, the quality of life at the start of the study is so high that no significant difference could be found.

In the following table, the data is assessed in columns:

- Condition/Study = Name of principal author, topic, number in the complete reference list;
- N = number of patients included in the survey;
- Design QoL = description of the design of the survey, used questionnaire;
- Test group = treated group under study;
- Control group = used comparison group if any;
- Results = major results of the survey.

Condition/Study	N	Design QoL	Test group	Control group	Results
Adler et al. 2009. (89). Depression.	91	Double-blind, Randomized Non-inferiority Trial. MADR Scale	Homeopathy Q potencies	Fluoxetine	Similar response rate.
Becker-Witt et al. (79, 80)	2851	Prospective observational study. MOS SF-36	Homeopathy	-	Significant and relevant improvement of the SF-36
Bordet et al. (85) Menopausal hot flushes. 6 months	438	Prospective observational study. Multicentric (99 MD) Not validated double QoL score	Homeopathy	-	Significant and relevant improvement on both QoL scores (daytime / sleep)
Dias-Brunini. 2002 (70) Asthma – pediatrics 6 months	51	Prospective observational study. AUQEI QoL score applied to children.	Homeopathy	-	QoL score from 42,27 to 54,94, significant statistical increase.
Goossens & al 2008 (86) Hay fever	74	Prospective observational non comparative study. RQLQ QoL	Homeopathy	-	Significant improvement after 3 and 4 weeks.
Guthlin et al 2001 (74) All conditions <4 years	951	Prospective observational study. MOS SF-36	Homeopathy	-	Number of patients too small to find valid results.
Guthlin et al 2003 (82) All conditions <4 years	750	Prospective observational study. MOS SF-36	Homeopathy	-	QoL improved in most dimensions highly significantly
Jong et al 2006 (76) response to Respiratory and ear complaints 7-14-28 days, final results 2006.	2055	Prospective observational study. HSQ-12; HSQ-5	Homeopathy	Conventional	No significant differences in duration of illness, treatment, patient satisfaction and adverse effects.
Heger et al 2001 (81) Respiratory and ear complaints 14-28 days	456	Prospective observational study. HSQ-12; HSQ-5 (64,3% ><56,6%), Adverse effects 7,8% versus 22,3%	Homeopathy	Conventional	Homeopathy at least as effective as conventional medical care
Hochstrasse B. 1999 (78) pregnancy <9 months	205	Prospective observational comparative study. SEIQoL	Homeopathy	Conventional	Lower QoL in the homeopathic group (two different populations, comparisons impossible)
Muscari-Tomaioi et al 2001 (75) Headache 6 months	53	Prospective observational study. MOS SF-36	Homeopathy	-	The mean and median scores of all QoL dimensions rose. Strongest results in the "bodily pain" and "vitality" parameters p<0.0001
Pomposelli 2009 (87) Diabetic polyneuropathy	61	Prospective observational study	Homeopathy	Conventional	Improvement of QoL and Cost saving 17,5%
Spence et al 2005 (84) Wide range of chronic conditions	6544	Prospective observational study	Homeopathy	-	Positive health changes in routine homeopathic hospital practice
Strosser et al 2000 (77) Vertigo 6 weeks	119	Double blind Comparative study. MOS SF-36	Homeopathy (Vertigoheel)	Conventional (Betahistin)	Significant amelioration of the physical and mental health with homeopathy. Equivalent efficacy of the two groups.
Thompson et al 2002 (71) Cancer 5 consultations later	52	Prospective observational study. EORTC QLQ-30 QoL score	Homeopathy	-	Improvement in 75% of the patients.
Thompson et al 2003 (68) Symptoms of oestrogen withdrawal in women – breast cancer.	40	Prospective observational study.	Homeopathy	-	Significant improvements in anxiety, depression and QoL.
Waive-Priven et al 2009 (88) Dermatology. DQLI + HR-QoL score	49	Prospective observational study.	Homeopathy	-	Positive dermatological and QoL outcomes.
Wassenhoven et al 2003 (73) All conditions 6 months	1025	Prospective observational study. MOS SF-36 & DUKE QoL scores	Homeopathy	-	QoL score differences : Allergic cond. +7,987; Gen. health problems +10,198; Bowels +8,189; Muscles-bones +0,764; Stress, anxiety, sadness +6,041; Nose, ears +4,677; skin +6,395. Small but significant statistical improvement.

Condition/Study	N	Design QoL	Test group	Control group	Results
Weber et al 2002 (72) Acute sinusitis	63	Non-randomised, controlled clinical trial. HCG-5 QoL score	Homeopathy + herbal ther.	Conventional therapy	Equally effective (or ineffective)
White et al 2003 (69) Asthma – pediatrics / 12 months	96	Randomised placebo controlled trial using QoL subscale of the Childhood Asthma Questionnaire	Homeopathy adjunct to conven- tional treatment	Placebo adjunct to conventional treatment	No statistically significant changes in the QoL score, small severity improvement. NB: very high initial QoL score
Witt et al 2005 (83) All conditions 3,12 and 24 months	3981	Prospective multicentre cohort study. QoL score	Homeopathy	-	Marked and sustained improvements.

THE RESULTS OF THE ‘COST-EFFICIENCY’-STUDIES

Studies about **Cost-Efficiency** of the treatment are mostly requested by the authorities, a **level IIIa of evidence** is obtained for all analyzed aspects.

The reason for this interest is multiple. The cost of the conventional medicine is more or less a problem for certain patients. The survival of our social security systems is threatened by these enormous costs.

The available data (15 studies – 9.938 patients) show that a reduction of the total cost for the patient is possible maintaining a global efficacy when using homeopathy.

Again, a first group of studies compares the same cohort of patients before and after the study. The control group is the group itself before treatment. The monetary savings achieved by practicing homeopathy are statistically and clinically significant for all diagnoses merged. Some diagnoses are especially analyzed such as otitis media, atopic eczema and allergies, rheumatoid arthritis and anxiety disorders.

A second group uses an external control group treated this time with a conventional treatment. The results of these studies confirm that homeopathic treatment in general practice allows savings under all conditions. Some data were especially analyzed such as the seasonal allergic rhinitis, asthma, atopic eczema, food related allergies, chronic allergic rhinitis, anxiety disorders and acute rhino-pharyngitis.

Finally as per conclusions of Prof. Claudia Witt (105): *“Patients with chronic diseases benefit more from homeopathy than from conventional medicine at approximately the same costs. Conclusion after 12 months follow-up of 315 adults and 178 children; half of the patients received homeopathic, the other half conventional medical care. In both groups, patients’ health status improved substantially, but improvement was greater in patients on homeopathic treatment. Overall costs, including those for doctor visits, medication, and hospital stays, were nearly identical for adults, but average costs were higher in homeopathically treated children.”*

GENERAL CONCLUSIONS OF THIS LITERATURE REVIEW

Besides the general analysis and conclusions about the effects of homeopathy, efficacy has been proved using as RCT evaluation, as well, rather than QoL scores for the allergies under all aspects. The prevalence of these problems is growing in the world population. For authorities this is also a very big problem, being the cause of absenteeism. An important social cost is linked to these problems. Homeopathy can be a cost effective and efficient solution.

Condition/Study	N	Design	Economic Survey	Test group	Control group	Results
Becker-Witt et al 2003 (90) Different chronic conditions	493	Prospective, comparative cohort study	Homeopathy and patients could opt for concomitant conventional therapy	Homeopathy and patients could opt for concomitant conventional therapy	Patients could opt for conventional therapy	Patients seeking homeopathic treatment had a better outcome overall compared with patients on conventional treatment.
Chaufferin 2000 (99)		Compilation of nationally available data (secondary sources)	Homeopathy	Homeopathy	-	Homeopathic medication prices per unit lower than allopathic ones (number of prescriptions unknown, though). Fewer reimbursements for homeopathic doctors, only 1 % of reimbursement of French national health insurance system
Frei et al 2001 (91) Acute otitis media	230	Prospective, uncontrolled interventional study	Homeopathy	Homeopathy	-	72% resolved within 12 hours, 28 % were given antibiotics. Conventional treatment was 14 % more expensive (109 SFR vs. 94,6 SFR)
Frenkel et al 2002 (92) Atopic and allergic disorders	48	Prospective, uncontrolled interventional study	Homeopathy primarily in addition to conventional treatment	Homeopathy primarily in addition to conventional treatment	-	Before intervention on average 3.1 different conventional drugs/patient after 1.6 (p=0.001). Before intervention 31 used conventional drugs (costs on average \$40) after intervention 35 (costs on average \$16). Significant changes in quality of life, less sick leave.
Güthlin et al 2003 (93) Different chronic conditions	750	Prospective, uncontrolled observational study	Homeopathy	Homeopathy	-	32% of patients reduced conventional drugs. Total costs to treat 89 patients were 7129 GBP (including medication, staff time and diagnostic procedures - 29 % of the costs for consultation, 22% for conventional drugs)
Haselen et al 1999 (98) Rheumatoid arthritis	89 (random sample out of 427)	Retrospective study	Homeopathy (n=89) Acupuncture (n=4)	Homeopathy (n=89) Acupuncture (n=4)	-	Savings by homeopathic treatment calculated by deducting costs for homeopathic medication from conventional medication (hypothetical) for same diagnosis and same duration amounted to 60.40 Pound Sterling.
Jain 2003 (100) Reduced costs by homeopathic drug prescription	109	Prospective uncontrolled observational study	Homeopathy	Homeopathy	-	Reducing conventional remedies use, 42.4 % costs saved even 71.1 % in chronic asthma.
Rossi et al. 2009 (103) Respiratory Diseases	105	Retrospective observational study	Homeopathy	Homeopathy	Conventional	26. % used CAM, patients were significantly younger and better educated. CAM mostly provided by MDs, median costs for single and entire treatment of 4 and 205 euro. CAM User scored efficacy of conventional therapy lower than non user (p<0,001)
Schafer et al. 2002 (94) Hay fever, asthma, atopic eczema, food hypersensitivity		Population-based nested case control study	Alternative Medicine	Alternative Medicine	No alternative medicine	Conventional Drug cost saving of £ 39,90/patient/year.
Sevar. 2005 (104) All conditions	455	Prospective cohort study.	Homeopathy	Homeopathy	-	At 3 months SF-12 score on physical dimension HM 51.8; CM 47.9 (p<0.05). Lowering of cost of care for patients from 45,74 € for CM to 27 € for HM. Lowering of cost of care for the social security system with 50 % for patients using HM.
Tateb et al. 2003 (102) Chronic allergic rhinitis.	300	Prospective, comparative cohort study	Homeopathy (HM)	Homeopathy (HM)	Conventional treatment (CM)	The homeopathic drug strategy produced equivalent results but less overall costs reimbursed by the national health system
Trichard et al 2003 (95) Anxiety disorders	394	Prospective, comparative cohort study	Homeopathy	Homeopathy	Conventional treatment	Comparable overall cost between both treatment strategies but less sick leave in the homeopathic group
Trichard et al 2003 (96) Acute Rhinopharyngitis	499	Prospective, comparative cohort study	Homeopathy	Homeopathy	Conventional Therapy (antibiotics)	Only costs for medication included – average overall cost 6.78 € of which 3.78 € were reimbursed
Trichard et al. 2003 (97)	5549	Cross-sectional descriptive survey	Homeopathy	Homeopathy	-	Following homeopathic treatment there were significant reductions in consultations with other specialists and generalists, and in the cost of treatment. € 370 compared with € 287
Wassenhoven et al 2004 (101) All conditions.	782	Observational unselected study and comparison with nationally available data (secondary sources)	Homeopathy	Homeopathy	-	The largest cost savings were made by patients with the worst ratings of their physical condition prior to seeking homeopathic treatment.
Witt et al. (105) Atopic eczema	135	Prospect., comparative cohort study	Homeopathy	Homeopathy	Conventional treatment	Comparable efficacy but fewer costs for the homeopathic group.

CHAPTER VI

INTERNAL EVIDENCE – HEURISTIC

Homeopathy is a medical practice aiming at strengthening the natural homeostasis of the body and stimulating the immune system. Homeopathy acts following the similarity principle; that means that the symptomatic patient is treated with a medicine containing a substance causing similar symptoms in a healthy person. For example onion can be the cause of a watery discharge of the nose and eyes. A medicine prepared from onion, namely *Allium cepa*, can treat patients who have these symptoms during a coryza or allergic rhinitis accompanied by irritating watery discharge from the nose.

The law of similars has to be respected during clinical and fundamental studies. Twenty years ago a new paradigm allowing explanation of the homeopathic effects had been developed. It is the paradigm of the “*Body signifiers*” (106). It explains why the law of similars has to be respected in research protocols on homeopathy; the tested medicine must be significant for the research subject (cell, plant, animal or human). A databank of experiments on homeopathy is regularly updated and available (107) today.

A. Pure experimentations or provings.

Homeopathic medicine is the result of the experimentation initiated by Hahnemann. This physician wanted to understand the effect of the prescribed medicines and that is the reason why he first experimented with these medicines on himself, and, later on, other volunteers.

These experiments on “healthy” volunteers has never ceased for two centuries.

The medicine is taken by a volunteer for at least two consecutive days. The symptoms, developed by the volunteer after taking the medicine, are observed and noted very carefully. Afterwards all these symptoms are converted into repertorial language (integrated into existing rubrics or creation of a new rubric). The quality of each collected symptom is more important than the quantity of symptoms. Each proving result (symptom linked to a homeopathic medicine) has to be confirmed by other experiments and, later on, in

clinical practice. These experiments are standardized now and are realized on a regular basis with placebo control (108).

As such, each symptom of the *Materia Medica* can be described with a certain level of evidence (109). The higher the level of evidence for the symptom linked to a medicine, the more the medicine used has a chance to cure the patient; that means the more this medicine can influence the organism to which it is administered.

The more “significant” symptoms the patient has in common with the medicine, the more spectacular and complete will be the effect of the medicine. This is the globality principle in homeopathy. See definition of homeopathy www.lmhint.net.

A pure experimentation (proving) can be compared with a qualitative experiment, phase I, in conventional medicine with some exceptions. A position paper on this issue is available on www.homeopathyeurope.org. The homeopathic pharmacopoeia contains several thousands of different medicines; for each medicine many modalities (110) of symptoms exist and are encoded in our homeopathic repertories.

The analysis of the provings’ publications authorizes a **level of evidence IIb** for this experimental step (111). An audit of all English provings’ publications done from 1945 to 1995 was published (112) in 1998 and other publications are in preparation. A **level of evidence I** for these experiments is more and more predictable (113).

At LMHI Congresses new, or confirmation of previous, provings are presented.

In May 2008 the following provings were presented (see *Proceedings*):

Hydrogenium peroxidatum – H2O2. Dominici G. Double-blind, randomized, placebo controlled design; 16 provers revealing several symptoms clinically verified on human and animals.

Latrodectus Mactans Tredecimguttatus. AFADH – Fayeton S. Open design; 8 provers revealing groups of symptoms clinically verified.

Potentilla Anserina. Jansen JP. Multi-centric, prospective, double-blind design; 10 provers revealing 27 groups of symptoms.

Plutonium's Peaceful Brother: **Neptunium muriaticum.** Lustig D. Placebo-controlled design; 19 provers revealing 315 symptoms distributed into 12 groups of characteristic symptoms.

Brazilian Pathogeneses: **Helleborus Niger.** Marim M. Third confirmation, multicentric international design; 4 groups of symptoms are regularly recorded.

Sutherlandia Frutescens. Ross A, Webster H, van der Hulst N. Double-blind, placebo-controlled design; 24 provers revealing 15 symptoms correlated with the traditional use of the plant (restorative tonic in HIV patients).

Erythrina Lysistemon (African Coral Tree). Ross A, de Beer E. Triple-blind, placebo-controlled design; 32 provers revealing 25 symptoms.

Lobelia Cardinalis. Scheepers L. Open design; 7 provers revealing 293 symptoms.

Galium Aparine. Scheepers L. Open design; 8 provers revealing 18 groups of symptoms.

Ytterbium Nitricum. Vicol M, Cristescu LM, Ivanciu NV, Dobre ML, Sumbasacu M, Oprea AM, Goiceanu DM, Dragusanu O, Binder-Hampel A, Stanciu AM, Struza CM. Open design; 13 provers revealing 32 symptoms.

Hecla Lava. Multicentric international design.

In May 2010 (LMHI Congress) the following proving was presented (see *Proceedings*):

Protea cynaroides. Botha I. Double-blind design; 70 provers (60 *verum*, 10 placebo) revealing 4 Mind stages and many specific symptoms.

At the same congress the same team answered the question: "Are provings reproducible?"

To answer this question the group of the Durban University (South Africa) (Botha I.) did a comparative survey between groups using different proving methodologies (C4 trituration, Sherr and Dream proving methodology) for a same homeopathic medicine. These results are also in the *Proceedings* of the 2010 LMHI Congress. The end result was the formulation of 1373 rubrics utilized for analysis purposes, resulting in 881 verified rubrics of *Protea cynaroides*. The hypothesis "0": "there is no difference in the symptoms experienced between two consecutive years (symptoms are reproducible)" $p > 0.05$ has been confirmed and is the highest in the group using C4 methodology. The C4 and Sherr methodologies are the most reproducible based on rubric presence.

In May 2010 (European Parliament Strasbourg Congress on Homeopathy) see *Proceeding*:

Morpho Menelaus Occidentalis. Renoux H. A double blind design (7,9,15,30CH, 200K, placebo) pathogenetic trial. 30 provers, 16 supervisors.

In December 2011 (LMHI Congress) the following provings were presented (see *proceedings*):

Strychnos henningsii. Ross A.H.A. A triple-blind proving design (30CH, placebo) using also blood testing and clinical measurements to assess the effects.

Malus communis. Jansen JP. A multi-center, prospective, double blind proving design (12K, 30Kn 200K).

Eriodyction californicum. Scheepers L. Double blind proving design (30K)

Bacopa monnieri (Brahmi). Gupta V. Double blind placebo controlled proving design.

Proving: Publications in International journals 2008

Argemone mexicana. Dey NR, Das KC, Rai Y. Multi-centric double-blind design, 38 provers (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. January-March 2008;Vol2,n°1:13-18.

Cephalandra Indica. Dey NR, Das KC, Rai Y. Multi-centric double-blind design, 17 provers (6c, 30c, 200c). *Indian Journal of Research in Homeopathy*. April-June 2008;Vol2,n°2:20-24.

Ficus religiosa. Dey NR, Das KC, Rai Y, Siddiqui VA, Singh R. Multi-centric double blind homeopathic pathogenetic trial. *Indian Journal of Research in Homeopathy*. July-September 2008;Vol2,n°3:10-14.

Paraffin. Rajpal, Siddiqui VS, Dey NR, Das KC, Rai Y, Singh VK. Multi-centric double-blind design, 43 provers (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. October-December 2008;Vol2,n°4:20-25.

Proving: Publications in International journals 2009

Pothos foetidus. Shaw R, Vikram Singh, Siddiqui VA, Rajpal, Vinay Singh Kr, Hari Singh, Mal PC, Bhakat AK. A multicentric double blind Homeopathic Pathogenetic Trial (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. January-March 2009;Vol3,n°1:18-22.

Aconitum napellus. Piltan D, Rist L, Simões-Wüst P, Saller R. Test of a homeopathic dilution of Aconitum napellus. A clinical, randomized, double-blind, controlled crossover study in healthy volunteers. Proving shows significant distinction between Aconitum C30 and placebo. *Forschende Komplementärmedizin*, 2009; 16:168-73.

Saraca indica. Nayak C, Siddiqui VA, Rajpal, Vinay Singh Kr, Hari Singh, Ramender Pal, Vikram Singh, Roy RK, Prakash S, Yogender Rai, Das KC. A multicentric double blind Homeopathic Pathogenetic Trial (6C,

30C). *Indian Journal of Research in Homeopathy*. April-June 2009;Vol3,n°2:32-37.

Cuscuta reflexa. Shaw R, Siddiqui VA, Rajpal, Vinay Singh Kr, Dey NR. A multicentric double blind Homeopathic Pathogenetic Trial (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. July-September 2009;Vol3,n°3:7-13.

Mimosa humilis. Nayak C, Vikram Singh, Siddiqui VA, Rajpal, Prakash S, Yogender Rai, Dey NR. A multicentric double blind Homeopathic Pathogenetic Trial (6C, 30C). *Indian Journal of Research in Homeopathy*. October-December 2009;Vol3,n°4:16-20.

Proving: Publications in International journals 2010

Skookum chuck. Siddiqui VA, Yogender Rai, Prakash S, Dey NR. A multicentric double blind Homeopathic Pathogenetic Trial (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. January-March 2010;Vol4,n°1:8-14.

Carica papaya. Rajpal, Anil Khurana, Siddiqui VA, Singh V.K., Dutta B.N., Shakti Dey, Jayant R.D.. A multicentric double blind Homeopathic Pathogenetic Trial (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. April-June 2010;Vol4,n°2:7-12.

Azadirachta indica. Rajpal, Anil Khurana, Vinay Kumar Singh, Keeta Bagai, Chaudhari CP, Jayant RD. A multicentric double blind Homeopathic Pathogenetic Trial (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. July-September 2010;Vol 4 n°3:10-16.
Ocinum sanctum. Rajpal, Vinay Kumar Singh, Roy RK, Chaudhari CP, Mal OC, Bhakat AK. A multicentric double blind Homeopathic Pathogenetic Trial (6C, 30C, 200C). *Indian Journal of Research in Homeopathy*. October-December 2010;Vol 4 n°4:1-6.

B. Clinical verification of the homeopathic symptoms.

Symptoms obtained by pure experimentation must be confirmed by clinical results; the clinical validity of every symptom linked to a homeopathic medicine, as well as the totality of the symptoms (global picture of the medicine) must be verified. Traditionally, experts in homeopathy were references for this clinical verification of homeopathic symptoms; this is **level of evidence IV**. Expert advice is very common in medicine, as example, the "ideal" value for the cholesterol in adults is actually, according to experts, 1.9g/l; it is the same level of evidence (UCL 2007).

The homeopathic medical doctor today uses computers in daily practice allowing a new approach for the clinical verification of homeopathic symptoms using a new type of statistical analysis.

Two statistical techniques are possible in case of retrospective analysis:

* Either considering only indisputable results of prescriptions, failures or spectacular positive results. The analysis consists of looking at a possible link between this result and the selected symptoms of the patients used for the choice of the medicine. This method approximates the traditional analyses of experts. The results (114) make a strong connection between the results obtained by pure experimentation and the clinical efficacy of the prescription. At the end of this process, a table of the characteristic symptoms (or groups of symptoms) forming the picture of a homeopathic medicine can be established and verified. See a published example (115) in the references.

Thanks to these statistical results, a **level of evidence IIIb** is reached and we hope that other groups will participate to reach **level of evidence IIIa** in the near future. The clinical verification of homeopathic symptoms is an internal validation of the basic principles of homeopathy and results can be used for improving the daily practice very soon.

* Or applying the theorem of Bayes on the same clinical database. Here all values are expressed as prevalence and compared to the remainder of the population (Likelihood ratio LR or probability factor as a link between the symptom of a medicine and the obtained clinical results). This method can be applied on a retrospective (115) as well as on a prospective design (116, 117, 118).

Table of recent publications of clinical verification of homeopathic symptoms.

Condition/Study	N	Design	N Symp	N Rem	Results
Van Wassenhoven. (114). (2005)	2148	LR retrospective	>230	100	Symptoms – Similarity – Globality
CCRH (115) Damiana (2007)	3032	Trad. Method	?	1	Symptoms
Rutten & all (120) (2008)	4094	LR Prospective	6	75	Similarity
Araujo (*). Anacardium orientale (2008)	5	Trad. Method	?	1	16 groups of symptoms – Similarity (constitution)
Gnaiger & all (*) (121) Petroleum (2008)	25	Trad. Method	?	1	6 groups of symptoms – Similarity (constitution)
Dominici (*) Hydrogenium peroxidatum (2008)	18	Trad. Method	10	1	Symptoms of proving – Similarity
AFADH (*) Latrodectus Tredicim Guttatus (2008)	4	Trad. Method	?	1	24 groups of symptoms – Similarity (constitution)
AFADH (*) Tarentula Lycosa (2008)	5	Trad. Method	?	1	36 groups of symptoms – Similarity (constitution)
Louis (*) Borax (2008)	12	Trad. Method	?	1	6 groups of symptoms – Similarity (constitution)
Lustig (*) Neptunium muriaticum (2008)	2	Trad. Method	?	1	1 groups of symptoms – Similarity (constitution)
Marim & all (*) (2008)	5	Trad. Method	?	4	5 groups of symptoms – Similarity (constitution)
Petrucci (*) Falcon Peregrinus Disciplinatus (2008)	8	Trad. Method	8	1	Symptoms of proving – Similarity
Pla (*) Salix Fragilis (2008)	2	Trad. Method	95	1	7 groups of symptoms - Similarity (constitution)
Scheepers & all (*) (2008)	37	Trad. Method	38	6	Symptoms + 13 groups of symptoms - Similarity (constitution)
Servais & all (*) Petroleum (2008)	11	Trad. Method	220	1	Symptoms
Stolper & all (*) (2008)	26	Trad. Method	23	2	Symptoms of proving – Similarity
Uyttenhove (*) Cheirantus cheiri (2008)	300	Trad. Method	6	1	Symptoms of proving – Similarity
Uyttenhove & all (*) Hecla Lava (2008)	262	Trad. Method	?	1	Symptoms of proving – Similarity
Chakraborty & all (122) Blatta orientalis (2008)	6184	Trad. Method	80	1	Symptoms
Chakraborty & all (123) Amooro rohituka (2008)	4706	Trad. Method	89	1	Symptoms
Chakraborty & all (124) Mentha piperita (2008)	6372	Trad. Method	105	1	Symptoms
Chakraborty & all (125) Ferrum picricum (2008)	3465	Trad. Method	70	1	Symptoms
Chakraborty & all (126) Fagopyrum esculentum (2009)	6675	Trad. Method	95	1	Symptoms
Chakraborty & all (127) Alstonia constricta (2009)	3854	Trad. Method	66	1	Symptoms
Chakraborty & all (128) Ephedra vulgaris (2009)	1657	Trad. Method	47	1	Symptoms
Chakraborty & all (129) Tarentula Hispanica (2009)	2794	Trad. Method	148	1	Symptoms
Chakraborty & all (130) Iris Tenax (2010)	2279	Trad. Method	29	1	Symptoms
Nayak & all (131) Glycyrrhiza glabra (2010)	278	Trad. Method	109	1	Symptoms
Nayak & all (132) Glycyrrhiza glabra (2010)	340	Trad. Method	43	1	Symptoms
Ross A.H.A. (*) Strychnos henningsii	?	Comparison with the use of the plant by traditional healers	?	1	Symptoms and syndromes
Chakraborty P.S., Ali S.A. (*)	?	Concomitant symptoms	?	19	Concomitant symptoms (modalities)

(*) Proceedings of 63rd LMHI congress 2008 (Belgium)

Total: **46.590 patients** are included in recent systematic clinical verification of homeopathic symptoms. This number will increase very rapidly with the creation of an international databank of clinical cases in Italy. (Cli-Fi-Col project).

CONCLUSIONS ON INTERNAL EVIDENCE:

Taking the obtained and verified results into account, homeopathy can be confirmed as a valid medical method based on evidences: pure experimentations on volunteers produce controlled series of symptoms confirmed by clinical verification on a relevant number of patients. Of course, more research is necessary and welcome but the obtained level of evidence justifies the maintenance and development of homeopathy in the framework of medicine.

CHAPTER VII

THE HOMEOPATHIC MEDICINE HAS A SPECIFIC ACTIVITY.

The nature of the homeopathic medicinal products is, for some, a factor of resistance (see Chapter I) even if the **level of evidence** for the efficacy of homeopathy within the general practice is already high as we have seen. In fact, 66% of the homeopathic prescriptions are molecular concentrations (see mechanism of action) and as such would not be questioned by the molecular paradigm. Demonstrating an effect of the highest homeopathic dilutions-dynamizations is a confirmation that there is more than the molecular paradigm; there is a place for other paradigms that could be applied for radiation, psychoanalysis, acupunctural stimulations, highly diluted-dynamized homeopathic preparations, etc.

Actually, the proof of the action of the highest dilutions-dynamizations has reached **level of evidence IIa** and even **level of evidence I** for some.

Several university professors investigated all the published literature about this subject at the request of the ECH (European Committee for Homeopathy) (133). New references are added for the period 2005-2009.

A/ The cheapest experimental model, easy to realize and reproduce, is probably “*the acetylcholine induced contraction of rat ileum*”. This is a validated scientific model (Chang FY, Lee SD et al. Rat gastrointestinal motor responses mediated via activation of neurokinin receptors. *J. Gastroenterol Hepatol* 1999;14, 39-45). This model was applied first to homeopathic preparations by A. Cristea, a Rumanian researcher, using this model for the verification of very high dilutions of Belladonna. The results were published. (*Bastide M (ed). Signals and Images. Kluwer Academic Publishers 1997;161-170*).

Professor Wolfgang SüB of the Institute of Pharmacy of the University of Leipzig used this model to test the transition of a homeopathic medicine (in this case, *Atropinum sulfuricum* D60) from the original liquid form to tablets. As usual, several controls were done. The monohydrate α -lactose tablets impregnated with a high dilution of *Atropinum* show a systematic efficacy opposite the anhydrous α -lactose tablets. This means that the quality of the tablets can be tested before pharmaceutical commercialisation (constant reproducibility). This very simple model shows that the activity of the high diluted homeo-

pathic medicines can be demonstrated. (Schmidt F, SüB WG, Nieber K. In-vitro Testung von homöopathischen Verdünnungen. *Biol. Med./Heft 1/February 2004 ;32-37*).

B/ It took some time before another scientific model could be accepted by the scientific community. The first publication was done in 1991, but it was only in 2004 that the results were accepted for publication by *Inflammation Research*, a peer reviewed scientific journal. This model is different than that of Benveniste; he used the same control but not the same activator.

Professors Marcel Roberfroid and Jean Cumps of the “University of Louvain”, department of Pharmacy, and respectively coordinator of a multi-centric European survey (4 laboratories) and responsible for the statistical analysis, wrote the protocols of this study that showed a clear inhibition of the degranulation of the human basophils by high dilutions of **histamine** (10^{-30} – 10^{-38} M). This inhibition becomes evident by the coloration of alcian blue. This multi-centric study is confirmed afterwards in three laboratories by using flux cytometry and in one laboratory using freed histamine. These observations are irrefutable acknowledged the editor of *Inflammation Research* (Belon P, Cumps J, Ennis M, Mannaioni PF, Roberfroid M, Sainte-Laudy J, Wiegant FAC. Histamine dilutions modulate basophil activation. *Inflamm. Res.* 2004 ;53 ;181-188), (Sainte-Laudy J, Belon P. Improvement of flow cytometric analysis of basophil activation inhibition by high histamine dilutions. A novel basophil specific marker: CD 203c. *Homeopathy.* 2005;95:3-8), (Sainte-Laudy J, Belon P. Use of four different flow cytometric protocols for the analysis of human basophil activation. Application to the study of the biological activity of high dilutions of histamine. *Inflamm. Res.* 2006;55:S23-S24). These results are now confirmed again by replication in others independent research centers (Chirumbolo S, Brizzi M, Ortolani R, Vella A, Bellavite P. Inhibition of CD203c membrane up-regulation in human basophils by high dilutions of histamine: a controlled replication study. *Inflamm. Res.* 2009, April).

C/ Since the fifties, research on high dilutions exists; quality and number of publications increased the last decade. Critical studies and meta-analyses were done but were often denied or even ignored (see *COST B4 supplement*

report EUR 19110 ISBN 92-828-7434-6). This research was never supported or even advised by the academic authorities.

Describing the most important surveys published in international journals, Professor Jean Cambar, Dean of the Faculty of Pharmacy of Bordeaux, confirms the effects of highly diluted homeopathic preparations. As example he quoted : The efficacy of very high dilutions of human and animal natural molecules (also called *endogenous molecules*), this was published several times in peer reviewed journals: *Int J Immunotherapy* 1987 ;3 :191-200 (**Thymulin** in mice, Bastide M.), *Int J Immunopharm* 1990 ;6 :211-214 (α/β interferon, Carriere V.), *J Vet & Human Toxicol* 1995 ;37(3) :259-260/ *Homeopathy* 2008;97:3-9 (**Thyroxine**, Endler PC.), *Int J Immunopathol and Pharmacol* 1996 ;9 :43-51 (**Bursin**, Youbicier-Simo BL.). The efficacy of very high dilutions, using pharmacological models, is published also in peer reviewed journals: *Pathophysiol Haemost Thromb* 2005;34:29-34 (Platelet aggregation in portal hypertension and its modification by ultra-low doses of aspirin, Eizayaga FX); *Thrombosis res* 2000;100:317-323 (Time related neutralization of two doses acetyl salicylic acid, Aguejof O.); *Thrombosis res* 1998;90:215-221 (Combination of two doses of acetyl salicylic acid: experimental study of arterial thrombosis, Belougne-Malfatti E.); *Thrombosis res* 2000;99:595-602 (Effects of acetyl salicylic acid therapy on an experimental thrombosis induced by laser beam, Aguejof O.); *Thrombosis res* 1998;89:123-127 (Thromboembolic complications several days after a single-dose administration of aspirin, Aguejof O.); *Thrombosis res* 1994;76 :225-229 (Acetyl salicylic acid in a vessel model, Doutremepuich C.) ; *Haemostasis* 1993;23 :8-12 (Effect of aspirin on embolization in an arterial model of laser-induced thrombus formation, Vesvres M.H.); *Thrombosis res* 1992;65:33-43 (In vitro platelets/endothelial cells interactions in presence of acetylsalicylic acid at various dosages, Lalanne M.C.); *Haemostasis* 1990;20 :99-105 (Acetyl salicylic acid in healthy volunteers, Doutremepuich C.); *Thrombosis res* 1987 ;48 :501-504 (Acetylsalicylic acid in healthy volunteers, Doutremepuich C). The oldest used model, the subject of several international publications is the *toxicologic* model (Arsenic, Phosphorus, Mercury, Cadmium, Cis-platina, Glutamate, Sulphate, Copper sulphate, etc...). It can be applied on plant and animal material, on cell cultures and even in clinical studies. This model is still used and is even the subject of cooperation between the Universities of Bern and Bologna, testing homeopathic treatments prepared from arsenic trioxide on plants. The germination of seeds and the length of the stems on the 7th day, are the analyzed variables. This group, under

the leadership of Dr Lucietta Betti, department DISTA of agro-environmental Science and Technology, University of Bologna, published 6 recent experiments.

A systematic review of the *in vitro* evidence of high homeopathic potencies was published in 2007 (134). The conclusions are that even experiments with a high methodological standard could demonstrate an effect of high potencies. No positive result was stable enough to be reproduced by all investigators. Among those that have been replicated by independent investigators the action of mercuric bichloride on hydrolases and especially the action of histamine of the Anti-IgE triggered basophile granulocyte degranulation seemed to be the most reproducible (see above).

The professors concluded: these experiments are conducted in controlled circumstances, with a sufficient amount of plants, animals or cells and with a statistically valid treatment. These facts are indisputable, statistically significant and, for some, reproducible, even if it is not possible to explain the obtained results with the molecular paradigm.

Several audits of these publications are available and may justify a **level of evidence I** (134, 135, 136). Seventy-five publications were evaluated by a German team, 105 articles were analyzed in a second audit examining the protecting effect against toxic substances (isopathic model). Seventy percent of these publications are of unquestionable quality and show the positive effect of the homeopathic medicines used. In a third audit, 76 of the 162 analyzed studies were classified as "best quality", the effects are meaningful and reproducible. (See also Mechanism of action).

Other examples, new results since 2007: references (140, 141, 142):

2008 – 63rd LMHI congress' proceedings:

Costa BGB, Siqueira CM, Barbosa GM, Portela MB, Soares RMA, Holandino C. Development of a new biotherapeutic of *Candida Albicans* to the treatment of oral candidiasis using yeast cells cultures, placebo and Nystatin® controlled design./

Siqueira CM, Costa B, Amorim AM, Conzalez M, Veiga VF, Lyrio C, Couceiro JN, Holandino C. Looking for a new biotherapeutic prepared from infectious influenza virus: an in vitro study. Virus H3N2, MDCK cells cultures, antiviral activity. Other references (143, 144, 145).

2010 – New publications.

The peer reviewed journal *Homeopathy*(137), published two special issues on biological models of homeopathy in 2009 and 2010 and concluded as such: "Above all this field is exciting and dynamic: there is a remarkable range of biological models of relevance to homeopathy, with encouraging progress in terms of quality and a growing number of positive findings. And we have not covered all the models in depth: for instance the work of Christian Doutremepuich's group on the effects of dilution of aspirin on blood clotting, the subject of several repetitions, is discussed only briefly. The replicability of experiments is a crucial criterion for their credibility. The multinational group led by Christian Endler and involving coauthors from Austria, Switzerland and Brazil address in this issue their bibliometric study of repetitions of fundamental research models. They found that 24 experimental models have been repeatedly investigated, 22 with similar inter-experiment results. They classify repetitions according to whether they came from the same group as the original report, or multicentre or independent work; and results as positive and similar, positive but qualitative different or negative. The most frequently and consistently replicable model is inhibition of basophil activation by high dilutions of histamine. But as Madeleine Ennis shows significant methodological issues remain. Methods vary between laboratories, although the same can be said of conventional studies. She suggests that following standardization another multicentre experiment be performed."

Once again results are very encouraging and are able to reach a significant evidence level, but more systematic standardized research is needed.

Medicine Nobel Prize winner Prof Luc Montagnier, does not hesitate now to support the idea of information transmitted through water solvent. This is the result of his findings published already in *Interdiscip Sci Comput Life Sci* (2009) 1:81-90 "Electromagnetic Signals Are Produced by Aqueous Nanostructures Derived from Bacterial DNA Sequences". In Strasburg, during the con-

gress "Homeopathy, a chance for Europe" (May 2010) he concluded: "Since 2005 we discovered that plasma from patients suffering of chronic degenerative diseases can emit low frequencies electromagnetic signals at high dilutions in water corresponding to the same frequencies of bacteria's DNA. These findings are confirming the idea of Water Memory and previous results obtained with, as example, the basophil activation model." At the XXIV GIRI symposium in Monaco (Nov. 2010) he presented also a second publication: Electromagnetic Detection of HIV DNA in the Blood of AIDS Patients Treated by Antiretroviral Therapy. *Interdiscip Sci Comput Life Sci*. 2009;1: 245–253 and he concluded that there is a highly sensitive detection system for chronic bacterial infections in human beings and animals. He also noted that serial dilution and agitation have found to be critical for the generation of electromagnetic signals.

A new area for research is now very active in laboratories in the world about the use of Homeopathy in viral infections? A first result has been published in 2010.

Bhaswati Bandyopadhyay & all. Decreased intensity of Japanese Encephalitis virus infection in chick chorioallantoic membrane under influence of ultradiluted Belladonna extract. *Indian Journal of Research in Homeopathy*. Vol 4, N°2, April-June 2010.

2011 – New publications.

EEG as control of the effects of homeopathic medicines! Totally independently of each other, two teams arrived to a similar conclusion; EEG can be a very objective "control tool" for the effects of homeopathic medicines. The first team (138) could demonstrate objective and specific changes in EEG of healthy volunteers during drug provings and the second team (139) did the same in laboratory rats; the effect of the homeopathic medicines are comparable to the effects of neurologic conventional drugs.

Guedes JRP, Carrasco S, Ferreira CM, Bonamin LV, Souza W, Goldenstein-Schainberg C. Ultra High Dilution of **Triiodothyronine** (T3 10CH) modifies cellular apoptosis in *Rana catesbeiana* tadpole tail in vitro. *Homeopathy* (2011) 100, 220-227.

PHYSICS OF HOMEOPATHIC MEDICINES

Introduction by Prof. Louis Rey†

(Abstract of a seminar in Rome 20-21 of October 2009: Ethique et Spiritualité de la Santé – Médecines traditionnelles et complémentaires. Recherches et orientations nouvelles)

A persistent issue in the assessment of homeopathy by classical academics, especially in the field of so-called “hard sciences”, is the fact that, in high and ultra-high dilutions, there are no more traces of any original chemical. Hence, they claim that these different solutions are, indeed, all the same and no more than the mere solvent itself. This radical assumption proved to be wrong, at least in the light of several centuries of careful clinical observations, which did show evidence, that high dilutions were not only active in therapeutics but that they also had distinct personalities, both properties which could not be found in the solvent used for their preparation. Quite obviously, this problem has been a definite challenge for all researchers in physics, chemistry and material sciences.

Different physical methods to assess high dilutions

A/ Nuclear Magnetic Resonance (RMN) by Izel Botha

This paper seeks to perform a meta-analysis of the findings of these studies and to draw a conclusion on the nature of homeopathic dilutions as well as the validity of performing this type of inquiry into the nature of homeopathically prepared medicines.

From the studies presented, two conclusions can be drawn, the first dealing with the evolution of the thinking processes associated with the studies that needed to be conducted. The initial studies, conducted by Ross (146) and Power (147), investigated the nature of Q potencies. These researchers acknowledged that the theories as to the molecular organization in solutions existed, but they refrained from conclusively interpreting the results in terms of those theories. Their research led to Cason (148) investigating the influence of the frequency of the NMR spectrometer on results obtained. Davies (149) and Malan (150) investigated the role of dilution on the physico-chemical structure of the homeopathic solutions, showing that information storage does take place in the solution, but that different dilution methods result in different solutions, even when the theoretical dilution level is equal. Malan's (150) mention of dilution level and succussion opened the door for investigation of the effect of various potentization methods. Hofmeyr (151), Lyell (152)

and Botha (153) each investigated different variables that may be introduced during the manufacturing process, particularly looking at the number of succussions and the effect of trituration. Erasmus (154) took this one step further by investigating the mechanics of the succussion process. These researchers interpreted their results based on the theories of Resch and Gutmann (155) and Anagnostatos (156).

This body of knowledge has inspired Allsopp (157) to look into the effect of energy transfer into the solution – whether it is imperative that the energy is imprinted mechanically by hand production of the remedies, or if it can equally be achieved through electromagnetic means. In comparing the studies, it is evident that both trituration and serial dilution change the physico-chemical properties of the solvent to produce distinct medicines.

Conclusions: The meta-analysis supports the conclusion that different potentization methods result in medicines with different physico-chemical properties. One can also conclude that NMR Spectroscopy is a valuable tool in assessing the physico-chemical effect that potentization methods have on the lactose and water/ethanol bases utilized in the manufacture of homeopathic medicines. It works well to study a single compound and it is not adapted to the investigation of a complex mix of different substances. NMR may be used for low potencies and only with the best available instrument. Other references, Weingärtner (158), Williams (159), Barnard (160), Young (161), Sach (162), Bol (163), Aabel (164), Milgrom (165), Anagnostatos (166), Bellavite (167), Smith (168), Antonchenko (169), Shaw (170).

New publication in the same area:

Demangeat JL. NMR water proton relaxation in unheated and heated ultrahigh aqueous dilutions of histamine: Evidence for an air-dependent supramolecular organization of water. *Journal of Molecular Liquids* 2009;144:32-39.

B/ A new Magnetic Resonance method by K. Lenger

The “homeopathic information” in high homeopathic potencies on sugar globule could be considered as photons with frequencies in the MHz-region by scientific evidence. These photons in high homeopathic potencies were detected by two magnetic resonance-methods (171, 172): firstly by the modified photomultiplier-method and secondly by the Tesla-coil method. Both methods allowed determination of physical properties of these photons: holistic, coherent quantum behavior, damping of the

magnetic field by resonance effect, at least two resonance frequencies in the MHz-region, frequency spectra after being excited by one of their characteristic resonance frequencies, measurability of the degree of potencies by separation of the photons from their carrier substances alcohol or sucrose by increasing the electromagnetic fields of their resonance frequencies. A device for measuring the degree of the potencies and their resonance frequencies must be developed for quality control of them in future. Further investigations about the stability of the remedies in different media: water, alcohol, sugar, are still necessary. A physical model must be developed in which way matter substance could be converted into energy, into photons by succussion in alcoholic dilutions and in triturations.

For a patient, the pathological pathways (173, 174) can be regulated by this treatment.

C/UV – Visible spectrometry

A promising approach was reached when the dilutions were studied near the upper limit of their ultra-violet absorption spectrum (200 to 400 nm). Rao, Roy, Bell and Hoover (175) obtained some interesting recordings for ultra-molecular solutions of 3 different products selected in totally different kingdom (*Natrium muriaticum*, *Pulsatilla*, *Lachesis*) and were able to discriminate them at the 30C level. Similar results were equally obtained by Pollack and Wexler working on Havit, *Apis mellifica* and *Histaminum*. This method, however, proved to be highly sensitive to rather unforeseen parameters, like the time of the day. Reproducibility has not yet been possible.

In the same area Wolf U, Wolf M, Heusser P, Thyrneysen A, Baumgartner S, presented at the 65th LMHI Congress the following study: Homeopathic Preparations of Quartz, Sulfur and Copper Sulfate assessed by U.V. Spectroscopy.

D/Raman spectroscopy

Different attempts have been done to see whether a close investigation of the Raman shift could help in discriminating the dilutions among themselves. Once more the operating conditions proved to be determinant: the position of the tube, recording done in a dark room and the same instrument. Under those conditions Rao (175) could demonstrate that the spectral peaks corresponding to different potencies of the same strain or dilutions of the same potency from different sources are different. Even if those differences are small, they look reproducible.

E/Dynamic Electrophotonic Capture: Gaz Discharge Visualization – EPC/GDV

The introduction of the so-called EPC/GDV technique in the research on high dilutions is a somewhat accidental and unforeseen event. It results from the pioneering work of Konstantin Korotkov who developed a completely new process to analyze “the energy fields” on multiple targets thanks to the analysis of the electrophotonic glow stimulated by a train of controlled pulses of a high-tension electromagnetic field, a technique based upon the Kirlian effect. Applied to ultra-molecular dilutions by Iris Bell (176), very small drops of liquid (0,02cc) gave successive glow images under electric discharge, which could be further processed thanks to the elaborative software of K. Korotkov. The triple analysis of their fractality (shape), size and brightness did show different patterns which, under well-selected conditions, could be species-specific, and Iris Bell discovered that a high dilution of *Natrium muriaticum* had definitely a different overall finger-print than its original solvent (ethanol in that particular case). It is most likely that this innovative technique might open perspectives in dilution research.

F/Calorimetric and Electric Measurements

In a completely different field, Elia, *et al.*, (177) were able to show that when a high dilution was mixed with an acid or a base, the heat release was much more important than it should be for a standard reference. He claimed that this was due to the fact that, in the case of high dilutions, an excess of energy was basically needed to “rupture” intrinsic structures (so-called dissipative structures) resulting to their preparation.

Similar discrepancies were also observed by Elia (178) when he measured the electric conductivity of high dilutions, an observation which was shared by Zacharias (179) and his group in Brazil when they compared succused high dilutions of Vincristine sulfate an inert solvent.

Another interesting approach in the field of electric measurements is provided by the use of Impedance spectroscopy. In that particular technique the behavior of a dilution is assessed as a dielectric medium in low frequencies and some preliminary research (Monod – Cemagref) did show that the loss angle (Tg delta) and the dielectric constant are substantially different from one dilution to its original solvent. Another team (180) published a paper on the “Effect of dielectric dispersion on potentised homeopathic medicines” and concluded that using this method it is possible to identify each homeopathic remedy in a solution even above Avogadro’s number. The same observation was confirmed by another team in India (181).

G/Thermoluminescence**(abstract Prof. Louis Rey)** (182, 183)

Low-temperature thermoluminescence is a very sensitive investigation tool and, for instance, could discriminate very easily different highly diluted alumina colloids that could not be distinguished by classical chemical analysis. On that base this method was used to study inter alia, potassium dichromate, sodium chloride and lithium chloride preparations made in D₂O. For potassium dichromate, the experiments carried out with Ilse Muchitsch and Michael Frass showed very clearly that their "finger prints" were totally different from the one of the heavy water alone even in dilutions above Avogadro's number.

Conclusions:

This rapid survey of investigations performed on ultra-molecular dilutions by different physical methods confirms that it is can be proven that, even beyond Avogadro's number, they are different from their pure solvent and also specific to the precise chemicals dissolved at the initial state of their preparation. Each dilution has its own personality and can be identified by its own "finger-print." Complex fluids carry much more information than could be expected and this provides a strong, positive background for homeopathy.

To explain the clinical facts even in very high dilutions and potentizations (remember that only 25 % of the daily delivery of homeopathic medicines in a pharmacy – 75 % being at molecular level), another scientific paradigm is needed. For many years another scientific paradigm has existed, the paradigm of *body signifiers* (184). With the existence of such a scientific framework, the nature of the homeopathic medicine begins to be understood and even identified.

MECHANISM OF ACTION OF HOMEOPATHIC MEDICINES – SUMMARY OF SOME ACTUAL KNOWLEDGE

There are first the well-documented paradoxical **low-dilution effects**. The basic idea of homeopathy is the exploitation of the paradoxical secondary effects of low doses of drugs. Secondly, reverse or paradoxical effects of drugs and toxins in living organisms as a function of dose or time are very widely observed in pharmacology and toxicology. They are variously termed hormesis (the stimulatory or beneficial effects of small doses of toxins), hormlignosis, Arndt-Schulz effects, rebound effects, dose-dependent reverse effects and paradoxical pharmacology (Calabrese and Blain, 2005 (189); 2006 (188); Bond, 2001 (187); Teixeira, 2007 (196); 2011 (197)). This, of course, does not address the question of ultra-molecular dilutions, but the majority of dispensed homeopathic medicines are not in the ultra-molecular range (De Gendt et al., 2011) (191).

Of course the most controversial aspect of homeopathy is its use of **ultra-molecular dilutions**. But again this is not a scientific black hole.

The HomBRex Database on Fundamental Research in Homeopathy (www.carstensstiftung.de/hombrex) includes details of about 1500 basic research experiments in homeopathy. Of these, 830 experiments employed ultra-molecular dilutions; in 745 of these at least one positive result was reported. A more recent meta-analysis evaluated 67 in-vitro biological experiments in 75 research publications and found high-potency effects were reported in nearly 75 % of all replicated studies; however, no positive result was stable enough to be reproduced by all investigators (Witt et al., 2007) (134).

The most reproduced series of in-vitro experiments in homeopathy are those using the model of the allergic response to antibody using the human basophil degranulation test. There are now 17 publications on inhibition of basophil activation by high dilutions of histamine, spanning over 25 years and including multi-centre and independent replications. There has been steady refinement of the method, including improved markers and the introduction of flow cytometry (Sainte Laudy and Belon, 2009 (195); Endler et al., 2010 (193)). There is a consistent peak at 16c (10^{-32}), well into the ultra-molecular range. These experiments have also yielded insights into possible mechanisms of action, for instance the response is highly specific to histamine; it is not induced by the structural analogue histidine, it appears to be mediated by H2 receptor-mediated inhibition of basophil activation and it is partly blocked by the H2 receptor antagonists ranitidine and cimetidine. (Belon et al 2004 (186); Chirumbolo S et al 2009 (190)).

Another cellular system that has been the subject of repeated experiments over a long period is the effect of ultra-molecular dilutions of aspirin on blood clotting (Eizyaga, 2007) (192). Recent work with 'knock-out' mice suggests that the effect is due to inhibition of COX-2 mediated PGI2 production in vascular endothelium (Aguejof, 2008) (185).

The most robust whole animal model is the effect of thyroxine on the rate of metamorphosis of frogs. This effect has been reproduced in multi-center experiments (Welles et al, 2007) (198) and by independent workers with different species of frog and with different outcome measures (Guedes et al, 2004) (194).

CHAPTER VIII

HOMEOPATHY IN VETERINARY PRACTICE

The advantages of the analysis of results in veterinary practice are various. The environment in which animals are living can be considered as stable and very similar for all of the animals considered. Studies on large animal cohorts are easier to realize than for human. A double-blind design is easier to obtain. Placebo effects are minimal. Of course the number of surveys is still few, but for two diagnoses, sufficient studies are published and reproduced; a “level of evidence I” could be obtained very soon.

These two considered diagnoses are infertility in cows (201, 202, 203) and mastitis in cows (204, 205, 213). These two problems have important consequences for public health; antibiotics (normally prescribed for mastitis) can be found, as residues, in the food chain. Therefore, the milk produced must be destroyed; the economic consequences for the sector are very important. Moreover, homeopathic treatment is the only one authorized by the European authorities in the framework of biological breeding. About efficacy, homeopathy and antibiotic treatment of mastitis do not differ that much.

Other results are coming from another farming activity: chickens are very sensitive to stress; when stressed, they are pecking each other resulting in important losses in production (206). The same happens for turkeys; they are very sensitive to haematomas caused by shocks during transportation. This problem can be reduced by 30 % with homeopathic treatment. The problem of regulation of sexual hormones of sows in farms (207) is important for the farmer and for the cost in pig production; homeopathy can offer a solution without “ethical” problems or risks for consumers.

European regulation of organic farming implies an extension of this type of research in the coming years.

http://ec.europa.eu/agriculture/organic/animal-welfare/health_en

http://ec.europa.eu/agriculture/organic/eu-policy/legislation_en

Council regulation (EC) N°834/2007 is binding and directly applicable in all EU Member States (applied from 1 January 2009).

European Parliament – Budget 2012 “AGRI/5227”. Pilot project – Coordinate research on the use of homeopathy and phytotherapy in livestock farming. Justification: antibiotic resistance is a growing worldwide problem. One

reason is the use of antibiotics in livestock farming. This is why research on alternative methods has to be moved forward.

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CONCLUSION

Today an overview of all veterinary clinical research in homeopathy has been facilitated by the creation of an International DATABASE located at the Karl and Veronica Carstens Stiftung in Essen Germany. www.carstens-stiftung.de/clinresvet/index.php

In the publication of this database in a journal (*Homeopathy* (2010);99:189-191) this database is presented as

a tool enabling researchers and veterinarians, skeptics and supporters to get a quick overview of the status of veterinary clinical research in homeopathy and alleviates the preparation of systematical reviews or may stimulate replication or even new studies.

The VetCR database contains about 300 entries of randomized clinical trials, non-randomized clinical trials, observational studies, drug provings, case reports and case series. Twenty-four clinical fields are covered and eleven different groups of species are included.

This databank will be updated regularly and consultation is free of charge. Do not hesitate to consider the value of homeopathy through veterinary clinical research by consulting this database.

CHAPTER IX

QUESTIONING HOMEOPATHIC MEDICINES

Considering homeopathy's individualize patient approach, the scientific framework is much broader than could be expected. Homeopathic physicians are mostly focused on research about individualization, similarity and globality. That does not exclude research on some diagnoses and a lot of indications are reaching a **IIIb level of evidence** and would be further considered for more research.

Examples without reference are from the **63rd LMHI Congress on Evidence Based Homeopathy (2008)**; later publications are referenced:

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Popowski P. **Dermatite atopique** et recherche clinique en médecine ambulatoire. Retrospective study on 27 patients.

Vander Brempt X, Cumps J, Capieaux E. Efficacité clinique de 2LALERG dans le **rhume des foins**. Double-blind placebo controlled study on 41 patients.

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were able to discontinue at least one medication, while the remaining patients (38%) reported a dose reduction in at least one medication. No side effects were reported during treatment. *Wien Klin Wochenschr.* 2012 Jan;124(1-2):11-7. Epub 2011 Dec 8.

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Clercq JM, Capieaux E, Jenaer M. Micro-immunotherapy applied to *paradontal diseases*. Follow-up of 20 patients. Jussara Diffini SM. **Oral health** of 6 to 14 year-old children treated with allopathy and homeopathy. Comparison study on 599 children.

Jussara Diffini S.M. Evaluation and comparison of **salivary conditions** of children with respiratory problems treated with allopathic and homeopathic medications. Comparison study on 90 patients.

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Teut M, Lütke R, Willich SN, Witt CM. Homeopathic treatment of elderly patients – A prospective observational study with 2 years follow-up of 83 patients. Proceedings 64th LMHI congress.

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Chiche JL. *Actea Racemosa* 30CH dans la **dystocie cervicale** pendant l'accouchement. Etude sur 24 parturiantes. Dungler T, Colas A. *Sanguinaria Canadensis* 7CH in the treatment of **flushes**. Study including 87 patients.

Honneger F, Lavalley V, Aguerre C, Cresp C, Desmonty-Minjon ML, Doussin-Dirks A, Ducos-Klingebliel S, Leblanc-Lebarazer A. **Mycoses vaginales récidivantes** et traitement homéopathique: un travail prospectif sur 13 patients.

Masson JL, Colas A. Prise en charge homéopathique des **bouffées de chaleur chez la femme ménopausée**. Prospective, multi-centric study on 438 patients. *Homeopathy* 2008 ;97(1) :10-15.

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Derbel, Belkadhi M, Villamo G, Mtiraoui A. **Rhinopharyngites** à répétition chez l'enfant, prise en charge en homéopathie. Etude prospective de 25 cas.

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Damaceno AMG, Bolognani F, Xavier MF, Mendes AP, Serpa C. Homeopathic therapy on a study of **Infantile Cerebral Palsy**. 9 years follow-up of 275 patients.

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Maia AP, Bolognani F, Mendes F, Fonseca G. The effect of homeopathic treatment in controlling **aggressiveness** in patients with cerebral palsy. 9 years follow-up in 57 patients.

Martins S, Bolognani F, Maia AP, Fraga CS, Mendes M. **Choreo Athetosis** condition and homeopathy. Follow-up of 75 patients.

Mateescu RA. **Attention Deficit Hyperactivity Disorder** in children and homeopathic treatment. Follow-up of 15 children.

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Mouyart MA. A list of first safe dilutions, a tool for all.

Sollie P. Availability and accessibility of raw materials and stocks. Problems in the daily pharmaceutical practice.

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Rheumatology :

Relton C, Smith C, Raw J, Walters C, Adebajo AO, Thomas KJ, Young TA. Healthcare provided by a homeopath as an adjunct to usual care for Fibromyalgia (FMS): results of a pilot RCT. *Homeopathy*. 2009;98:77-82.

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Traumatology – Toxicology :

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CHAPTER X

HOMEOPATHY AND EPIDEMIC DISEASES:

History

Although its efficacy has been demonstrated in the treatment of several individuals suffering from acute or chronic diseases, a historical review shows homeopathy's greatest asset appears to be in the treatment of epidemic diseases. There are impressive examples of such broader applications of homeopathy in the 19th and 20th centuries.

The founder of homeopathy, Dr. S. Hahnemann, initiated the methodology for the treatment epidemic diseases with homeopathy. This approach he called the *genus epidemicus*, meaning that a treatment protocol of an epidemic disease is designed based on the collected signs and symptoms of a large group of patients. This is opposed to the treatment of non-epidemic diseases in which for each different patient an individual remedy is selected based on the unique expression of the disease in the individual. In giving an historical overview on the use of homeopathy in epidemic diseases, Bedayn (219) writes:

"The curative results of the *genus epidemicus* were so positive during the epidemics in the ensuing decades that they not only cured the majority of those affected where nothing else had worked, but they also drew international acclaim towards homeopathy, the new, the rational, medicine. There is something intrinsically powerful about the success of homeopathy in curing large populations that is undeniably attractive to anyone gifted with the power of observation, and it was through these early cures with epidemics that Hahnemann was able to quickly and widely spread the word: Homeopathy."

Using the *genus epidemicus* principle, homeopaths impressed the medical establishment with their results. Here are a few quotes to illustrate this:

- *General*: "In epidemics the mortality per 100 patients is 1/2 to 1/8 in homeopathic hospitals (a century ago there were several homeopathic hospitals in the US) compared to allopathic hospitals." (Bradford, 1900) (220)
- *General*: "Homeopathy had become very popular in North America during its early years due to its amazing successes obtained by the 'old guard' during the epidemics – epidemics of diphtheria, scarlet fever, cholera, malaria, yellow fever." (From its Roots Upwards, Interview with *André Saine*, N.D., D.H.A.N.P., Vienna January 1994) (221)
- *General*: "Ever since Samuel Hahnemann homeopathy has time and again been able to successfully treat epidemics/pandemics with a small number of remedies." (*Stahl, Hadulla, Richter*, 2006) (222)
- *Cholera*: "In Russia in the years 1830 and 1831 homeopathy was used to treat 1270 cholera patients in the provinces Saratoff, Tambtoff and Twer: 1162 of those were cured, 108 died... similar rates in the results of homeopathic treatment for cholera were observed in Hungary, Mähren and Vienna." (Gebhardt, 1929) (223)
- *Cholera*: "When in the year 1854 cholera came to Palermo 1513 soldiers fell ill ... Of these 902 were treated with allopathy of which 386 died, a bit more than 42 %; 611 were treated with homeopathy, of which only 25, so almost 4 %, died.
In the abovementioned years cholera also visited the Caribbean, and on the 'pearl' of these islands, Barbados, 2113 people fell ill. Of the 346 treated with allopathy 154 died, but of the 1767 treated with homeopathy only 370." (Gebhardt, 1929) (223)
- *Cholera*: "3 % of the cholera patients under homeopathic treatment died (Cincinnati USA 1849). Mortality rate of cholera patients under allopathic treatment was 40-70 %." (Humphreys 1849) (224)
- *Spanish influenza*: "Perhaps the most recent use of homeopathy in a major epidemic was during the Influenza Pandemic of 1918. The Journal of the American Institute for Homeopathy, May, 1921, had a long article about the use of homeopathy in the flu epidemic. Dr. T A McCann, from Dayton, Ohio reported that 24,000 cases of flu treated allopathically had a mortality rate of 28.2 % while 26,000 cases of flu treated homeopathically had a mortality rate of 1.05 %. This last figure was supported by Dean W.A. Pearson of Philadelphia (Hahnemann College) who collected 26,795 cases of flu treated with homeopathy with the above result." (Winston 2006) (225)
- *Spanish influenza*: "Homeopathy has been used with great degree of success in influenza and other epidemics for 200 years ... In 1918 flu pandemic homeopaths reported around 1% mortality in their cases, while conven-

tional doctors were losing 30 % of their patients." [www.lifemedical.us/flu] NB: The Spanish influenza virus we know now was an avian virus. Approximately 40 million people died in just 18 months.

- *Spanish influenza*: "Dean W.A. Pearson of Philadelphia collected 26,795 cases of influenza treated by homeopathic physicians with a mortality of 1.05 %, while the average old school mortality was 30 %. Explanation: conventional treatment of folks with flu caused at least 8038 deaths while the homeopaths lost only 281 patients. That is a statistically significant difference." "Thirty physicians in Connecticut responded to my request for data. They reported 6,602 cases with 55 deaths, which is less than 1 %. In the transport service (during WWI) I had 81 cases on the way over. All recovered and were landed. Every man received homeopathic treatment. One ship (using conventional therapy) lost 31 on the way. H.A. Roberts, MD, Derby, Connecticut." [Explanation: a number of homeopathic physicians served in the Armed Forces during WW1 and made use of their homeopathic training. (Dearborn, 1923) (226) ; (Dewey, 1921)(227)
- *Spanish influenza*: "The most severe epidemic of all time was the Great Influenza Pandemic of 1918. Twenty percent of the entire world population was infected and 20-40 million people died. The epidemic was so devastating that the average lifespan in the United States was decreased by ten years. During this epidemic homeopathic medicines were used widely both for treatment and as prophylaxis. The average mortality under standard treatment ran from 2.5-10 %, while 1 % or fewer patients died under homeopathic treatment." (Hoover, 2006)(228)
- *Yellow Fever in USA*: "Homeopathy had become very popular in North America during its early years due to its amazing successes obtained by the "old guard" during the epidemics – epidemics of diphtheria, scarlet fever, cholera, malaria, yellow fever – especially yellow fever; the death rate for that was 55 % when allopathic treatment was used, but less than 5 % in cases with homeopathic treatment; and it was the same for cholera. It is here with the 'old guard' that homeopathy obtained its golden letters." ('From its Roots Upwards', Interview with *André Saine*, ND, DHANP, Vienna, January 1994.) (221)

These are clearly impressive figures, certainly if we compare them with the results of contemporary regular treatment. Considering the advances made in conventional medicine in the past century the question arises though whether homeopathy should still play a role in treating epidemic diseases.

Homeopathy and Epidemic Diseases Today

Towards the end of the 1880's, Homeopathy and conventional medicine were equally well accepted by the public. Conventional medical doctors in the US lobbied the government in the early 1900s and legislation was passed giving them the exclusive right to diagnose and treat medical conditions. With the US taking the lead in the world, homeopathy went into a decline. Homeopathic hospitals were closed. The light of homeopathy was kept alive by smaller number of homeopaths, but many lost track of what is called Hahnemannian homeopathy and as a science little progress was made.

This changed in the last decades of the 20th century. Homeopathy flourished again and, especially in the treatment of chronic diseases, great advances were made.

If we look at homeopathy today, the use of the *genus epidemicus* approach for epidemic diseases is marginal. In part, this is because epidemic diseases like those mentioned above hardly play a role anymore in the West. Homeopaths that went to developing countries to help those for whom often no medical care is available at all were strongly confronted with epidemic diseases. They once again started to treat epidemic diseases and experienced how successful homeopathy still is for these conditions.

Why Homeopathy Should Play a Role in Treating Epidemics?

Homeopathy does not stand in the way of effective treatment for patients but rather complements available conventional treatment.

- It is not the policy of the major homeopathic organizations in the world to advise patients against the use of conventional medicine and this includes the treatment of epidemic diseases. Patients that are not on conventional therapy because their case has not reached a critical level yet are observed to get improved health and increased immunity, thus postponing the need for conventional therapy. Homeopathic treatment boosts the immune system and side effects from conventional treatments are reduced significantly if patients also take homeopathic treatment. This represents a clear win-win situation.
- Conventional medical care is non-existent or limitedly available in many areas or only available to the very rich. Homeopathy can at least help this situation. Also when conventional therapy does not work any more homeopaths have regularly observed that these patients do respond to homeopathic treatment.

- Therapy resistance is an increasing problem making conventional medicine inactive and alternative approaches dearly needed. For the major epidemics in Africa – malaria, TB and HIV – this is a serious problem. The problems surrounding resistance are finding increasing acknowledgment within the healthcare community. "The threat of large-scale drug resistance is 'real and scary.'" (Marani 2007) (229)
"Resistance develops naturally, in response to the selective pressure from drugs or from the body's own immune system." (World Bank 2003) (230)
- Vaccination programs are not available for many diseases that keep undermining the health and development of developing countries. Homeopathy can help these populations as seen before.

We suggest that homeopathy could play an important role in the treatment of these diseases and that funds would be available to study this further. The above data from history support this idea, and current observations confirm that also for the epidemics today homeopathy is still effective.

There are several reasons why the homeopathic option for epidemic diseases deserves serious consideration:

- Homeopathic remedies create no side-effects
- Homeopathy is safe for pregnant women, babies and elderly people
- Homeopathic remedies are inexpensive
- Production, storage and distribution of homeopathic remedies is simple
- Homeopathy does not induce therapy resistance
- Homeopathic treatment does not create more dangerous viruses and bacteria
- Homeopathy has been effective in many epidemics in the past and indications are very strong that it is effective in today's epidemics as well

To prepare future surveys Kirkby R and Herscu P published the paper "Homeopathic trial design in influenza treatment" in the journal *Homeopathy* 2010;99:69-75 reviewing the published studies on this topic.

Some examples of contemporary publications on homeopathy in epidemic diseases:

Cholera: A pilot study of homeopathic treatment of cholera during an epidemic in Peru appeared to show that it was effective. A subsequent double blind study showed no difference between active homeopathic treatment and placebo treatment. Various technical problems were encountered (231). Further research is certainly needed.

We would remember here that results of such research depend largely of the sample size. Looking at childhood diarrhea, Dr J. Jacob. demonstrated this very well and concluded: "Previous studies have shown a positive treatment effect of individualized homeopathic treatment for acute childhood diarrhoea, but sample sizes were small and results were just at or near the level of statistical significance. Because all three studies followed the same basic study design, the combined data from these three studies were analyzed to obtain greater statistical power. Methods: Three double blind clinical trials of diarrhoea in 242 children ages 6 months to 5 years were analyzed as 1 group. Children were randomized to receive either an individualized homeopathic medicine or placebo to be taken as a single dose after each unformed stool for 5 days. Parents recorded daily stools on diary cards, and health workers made home visits daily to monitor children. The duration of diarrhoea was defined as the time until there were less than 3 unformed stools per day for 2 consecutive days. A meta-analysis of the effect-size difference of the three studies was also conducted.

Results: Combined analysis shows a duration of diarrhoea of 3.3 days in the homeopathy group compared with 4.1 in the placebo group ($P = 0.008$). The meta-analysis shows a consistent effect-size difference of approximately 0.66 day ($P = 0.008$).

Conclusions: The results from these studies confirm that individualized homeopathic treatment decreases the duration of acute childhood diarrhoea and suggest that larger sample sizes be used in future homeopathic research to ensure adequate statistical power. Homeopathy should be considered for use as an adjunct to oral rehydration for this illness." (232)

Leptospirosis: Homeopathy is associated with dramatic reduction in Leptospirosis infection in the Cuban population. This publication (July 2010) (233) provides fascinating evidence that a highly dilute substance, prepared according to homeopathic principles, may contribute to the prevention of Leptospirosis, also known as Weil's Disease. In Cuba, Leptospirosis is recorded by an efficient national surveillance program. Its incidence correlates closely with heavy rainfall and subsequent flooding. In late 2007, in response to a developing epidemic, and with only enough vaccine to treat 15,000 high-risk people, the government decided to treat the entire population of the region, over one year of age, with a homeopathic medicine. This was prepared from the inactivated causative organism provided by the Cuban National Vaccine Institute.

The homeopathic medicine was given to the 2.3 million population of the provinces usually worst affected. Within a few weeks the number of cases had fallen from 38 to 4 cases per 100,000 per week, significantly fewer than the historically-based forecast for those weeks of the year. The 8.8 million population of the other provinces did not receive homeopathic treatment and the incidence was as forecast. The effect appeared to be sustained: there was an 84 % reduction in infection in the treated region in the following year (2008) when, for the first time, incidence did not correlate with rainfall. In the same period, incidence in the untreated region increased by 22 %.

"Infectious diseases are still the bane of humanity, particularly in the developing world", states Dr Sara Eames, President of the Faculty of Homeopathy. "Anything which appears to reduce infection rates in a potentially fatal infection, particularly when it can be prepared and delivered quickly, safely and cost effectively, has to be taken seriously and studied further."

Dr Peter Fisher, Editor of *Homeopathy*, notes "This is a very large study and its results, if confirmed, have huge potential impact. We need more research into the effectiveness of homeopathic preparations in preventing infectious diseases, complications, and the economic viability of a homeopathic approach."

Influenza: Everybody is aware of the audit of the Cochrane organization about efficacy of a homeopathic medicine *Oscillocochinum* in the treatment of influenza (234). They updated the electronic searches on the Cochrane Central Register of Controlled Trials CENTRAL (*The Cochrane Library* Issue 1, 2006); MEDLINE (January 1966 to February 2006) and EMBASE (1980 to February 2006). The manufacturers of *Oscillocochinum* were contacted for information. Seven studies were included in the review, three prevention trials (number of participants (n) = 2265) and four treatment trials (n = 1194). Only two studies reported sufficient information to complete data extraction fully. There was no evidence that homeopathic treatment can prevent influenza-like syndrome (relative risk (RR) 0.64, 95 % confidence interval (CI) 0.28 to 1.43). *Oscillocochinum* treatment reduced the length of influenza illness by 0.28 days (95 % CI 0.50 to 0.06). *Oscillocochinum* also increased the chances that a patient considered treatment to be effective (RR 1.08; 95 % CI 1.17 to 1.00). Influenza (the flu) is a highly infectious respiratory disease caused by viruses. Other than treatments for complications (such as pneumonia) conventional medical treatment is bed rest. Homeopathy is a system based on 'curing like with like', often using highly diluted sub-

stances. *Oscillocochinum* is a homeopathic preparation manufactured from wild duck heart and liver (common sources of influenza). It is claimed that *Oscillocochinum* (or similar homeopathic medicines) can be taken either regularly over the winter months to prevent influenza or as a treatment. Trials do not show that homeopathic *Oscillocochinum* can prevent influenza. However, taking homeopathic *Oscillocochinum* once one has influenza might shorten the illness, but more research is needed.

During winter 2009/2010 a flu pandemic situation was recorded and followed day by day by the W.H.O. and all national authorities. As international organization, the LMHI asked to report about the use of homeopathy during this pandemic period.

For France: 17 physicians participated, 259 cases were collected and the most prescribed (123 times) remedy was Bryonia (symptoms, including high fever and asthenia, are aggravated by motion), followed by *Nux vomica*, *Pulsatilla*, *Gelsemium*, *Arsenicum album*, *Baptisia*, *China*, *Hepar sulphuris calc.*, *Phosphorus*, *Eupatorium perfoliatum*, *Belladonna*, *Sepia*, *Influenzinum*, etc. When the personal global (*simillimum*) remedy was known for the patient it was almost efficient (5 times used). Most cases were solved in 2 or 3 days. Post-flu asthenia has been described and a second remedy was then needed.

For Belgium: 92 patients were included in this report from only 3 physicians, 38 patients were between 15 and 40 years old. *Gelsemium* (headache, fever, asthenia, pain in muscles and bones) and *Anisum stellatum* (added to the same symptoms, deep and difficult cough, the disease seems to be more aggressive in Belgium than in France, this remedy is near Bryonia for general complaints) were prescribed 27 times each, followed by Euphrasia (11 times), *Arsenicum album*, *Baptisia tinctoria*, *Influenzinum*, *Oscillocochinum*. Only two complications developed, (bronchitis) one time easily treated with *Anisum stellatum*, antibiotics needed the other time. Most of cases solved in 2 or 3 days. It has been quoted that none of the patients having asked for a preventive treatment (once a week during the epidemic period) with *Influenzinum*, *Mucococchinum* or *Oscillocochinum* did present flu symptoms.

For Austria: The situation was evaluated and more than 300 patients were reported from 30 physicians. 27 different remedies were used adapted to the situation. Most quoted remedies were *Bryonia alba*, *Belladonna*, *Gelsemium*, *Influenzinum*, *Eupatorium perfoliatum*, *Arsenicum album*, *Oscillocochinum*, *Nux vomica*. Several times the

intake of the known global personal remedy (simillimum) was sufficient to solve the case very fast. Most of the cases were solved in the 2 or 3 following days.

Of course, these flu reports are not controlled systematic recording, more systematic and structured cases 'collections would be needed to assess the real value of homeopathy in case of epidemic situation. But the daily practice includes specific attention and treatments for these cases looking at each patient' symptoms individually. More research is needed and foreseen through the activities of the ISCHI (a scientific committee dedicated to Influenza and Homeopathy). This time no real *genus epidemicus* came out very clearly even if **Bryonia** (or *Anisum stellatum*) and **Gelsemium** seems to be the most frequently and efficiently used remedies.

Dengue: A survey in Thailand suggest that *Eupatorium perfoliatum* 200C may be beneficial for reducing individual susceptibility to dengue virus. Confirmation is needed. Teerachaisakul M. *Proceedings* of the 66th LMHI congress in India.

Chikungunya: *Bryonia alba* 30C was better than placebo in decreasing the incidence of this viral fever in Kerala (n=19750 *Bryonia* group, n=18479 placebo group). Nair K.R.J. *Proceedings* of the 66th LMHI Congress in India.

CONCLUSION

It would be irresponsible not to investigate seriously the observations made over two centuries by thousands of homeopaths concerning the homeopathic treatment of a wide variety of epidemic diseases.

GENERAL CONCLUSIONS

- Homeopathy is mostly used in medicine in the framework of general practice (but also by gynaecologists, pediatricians, etc) and is used by patients of all ages.
- Respect for patients' rights dictates that the patient must be informed about all possible therapies that could be used to improve his/her health and also about the therapeutic possibilities of homeopathic medicines, even when in hospital.
- The absence of a correct medical diagnosis at the start of a treatment is currently the only possible risk when using homeopathy as treatment. That is why it is necessary that the practice of homeopathy is dedicated to medical doctors.
- The **level of evidence** obtained for numerous diagnoses is sufficient to accredit homeopathic practice in the scientific framework of general practice.
- The use of homeopathy in general practice may imply a reduction in costs for public health. These savings are coming from a reduction of prescribed conventional remedies, a reduction in the number of consultations and a reduction in the number of days absent from work
- The number of competent homeopathic physicians is not sufficient to cover the demand of the population. Therefore it is important to promote information sessions and homeopathic education in the framework of general practice.
University research on homeopathy must be encouraged, stimulated and supported by public health authorities.
- Basic research results and veterinary research results are confirming the obtained results in humans. This is a specific effect supported by a new scientific paradigm.
- The internal evidence is validating and confirming the effects of the medical homeopathic method.

The facts presented in this report are consistent. Homeopathy must be accepted in the scientific framework of medicine, especially in the general medical practice framework. Research must be supported and amplified. Objective information is needed for patients. Education in homeopathy is encouraged in the framework of medicine.

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