

GUIDE TO
HOMEOPATHY

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This guide was written to provide notions on homeopathic medicine to doctors, veterinarians, dentists, pharmacists and all health professionals who wish to acquire knowledge on the subject. It was drafted with the aim of helping anyone who deals with health to provide interested citizens with informed answers on the subject.

For further information on:

- *how to contact homeopathic doctors in Italy*
- *how to attend post-graduate training courses in homeopathic medicine*
- *scientific references*

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PREFACE

Paolo Biasci

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Homeopathy was born in the first half of the nineteenth century based on the principles formulated by the German physician Samuel Hahnemann, among which the best known is that of the similitude "similia similibus curentur".

Currently, based on EU and national regulations, homeopathic medicines are classified as such and are required to obtain a Marketing Authorization (AIC). The doctors who practice it are included in special lists set up by the Provincial Orders of Surgeons and Dentists, after carrying out an evaluation of their educational path.

The use of homeopathy is widespread among the European population and affects all age groups, including the paediatric one.

At a time when great importance is given to evidence-based medicine, however, the lack of rigorous and reproducible scientific data inherent to homeopathic therapies emerges. This aspect, linked to multiple factors, some of which are inherent in the homeopathic medicine, and in the methodology correlated to its use, undoubtedly represents a critical aspect towards consensus and a spread within the international scientific medical world. Although it actually emerges that most of those who turn to homeopathy as a method of treatment, declares an improvement in the quality of life even in significant pathological situations, criticism emerges cyclically, sometimes a very harsh one, against homeopathy even in relation to dramatic events resulting from a unilaterally homeopathic approach to particularly important pathologies (eg bronchial asthma).

In light of these aspects, it is evident that this subject is currently included among the complementary medicines, signifying a possible supporting role in the course of treatment, where expressly requested, always bearing in mind the safety of the patient and not to leave out certified efficacy therapies.

As paediatricians, we are daily committed to protecting the health of our little patients, guaranteeing them therapies that are supported by shared guidelines and/or good clinical practices, acting according to science and conscience and in a constant dialogue/comparison with families.

Possible complementary therapeutic treatments can find space, if considered useful, based on specific skills and an accurate clinical evaluation.

In conclusion, we hope that this new guide will be a useful tool for those who want to improve their knowledge of homeopathy.

PREFACE

Franco Vimercati

*Chairman FISM
Italian Federation of
Medical Scientific Societies*

Complementary Medicine (CAM) is a much debated topic, especially in recent times, and the debate concerning homeopathy is particularly lively because on the one hand there is also very severe criticism from the scientific community that questions both basic principles of this discipline and its effectiveness, on the other hand we find a conspicuous number of patients who use it (about 15% of the population, Eurispes 2017 data), ready to confirm its positive effects.

In recent years, an integration model has been hoped for, according to which CAMs can complement the Academic Medicine by allowing the doctor to deal with the clinical problem with a wider range of available therapies.

It should be remembered, moreover, that at the provincial Order of Medical Doctors there are registers for the enrolment of physicians who have successfully completed training courses in homeopathy and in other complementary disciplines, according to rules issued by the State Regions Conference; therefore, in fact, within the Medical Orders there is already this support which is at risks of being only administrative, in the absence of an effective communication between the two sectors, the conventional one and the complementary one.

In the same perspective, the Federation of Italian Scientific Medical Societies (FISM), in which I hold the role of Chairman, has for some years established an internal commission that welcomes the CAM associations registered with the FISM, with the aim of tackling problems concerning this sector of medical activity, precisely in the belief that the topic "health" has such complex branches that it cannot be dealt with in such a restricted area as that represented by medicine considered only as therapy, if it is true what the WHO established in 1948, that health is based on the achievement of both physical and mental well-being of the individual.

Personally, it is not my intention to go into the topics of the debate on the effectiveness of CAM and homeopathy in particular, but I believe that the medical culture must develop around 360 degrees, the only way to guarantee the best protection of health.

We must ask ourselves: what would a doctor do if his patient asked him what it is and what the homeopathic remedy he is using is for or if his child, who has taken a whole box of a homeopathic remedy, is running some risks? Well a document that illustrates objectively the theoretical and practical aspects of homeopathy can be useful to that doctor, to have an idea, to be able to give an answer. Therefore, I consider SIOMI's initiative certainly appreciable, setting itself the goal not to make followers but to illustrate the characteristics of the methodology of Homeopathic Medicine, the principles on which it is based, the situation of scientific research, its possibilities and its limits. An easy to read tool and certainly useful to the doctor in their professional activity.

PREFACE

Gaetano Penocchio

*Chairman FNOVI
National Federation of
Italian Veterinary Orders*

Fnovi is convinced that the professional activity of the veterinary doctor must always be based on Article 8 - "Behavior according to science, conscience and professionalism" of the Code of Conduct and that CAMs are the exclusive competence of the veterinary doctors enlisted in the Register as clearly expressed by Article 31 - "Non-conventional medicines". The practice of non-conventional medicines in the veterinary field is the exclusive responsibility of the veterinary physician. This must be carried out in compliance with professional duties and dignity and in the exclusive field of direct and non-delegable professional responsibility, in order to protect animal health and welfare.

The therapeutic knowledge of the veterinary doctor must be as broad as possible to face and treat all pathologies and suffering conditions and to prevent diseases, giving shape to the concept of One Health.

Several and known are the challenges that the veterinary medical profession faces every day, in a world where "dr.google" bestows diagnoses, where resistance to antimicrobials kills victims, where climate change strengthens pathogens and weakens the tools to fight them.

So all the energies and possibilities are welcome.

For Fnovi it is not a question of validating, yet to grant veterinarians the freedom to choose the most appropriate therapeutic system for each patient and every situation.

This is the reason why long ago Fnovi drafted the guidelines on health advertising, to fill an old and increasingly anachronistic regulatory gap that hinders professionals, patients and owners.

PREFACE

Andrea Mandelli

*Chairman FOFI
Federation of Associations
of Italian Pharmacists*

Informing the patient about the therapies prescribed by the doctor, making clear what he did not understand, solving their doubts and satisfying their requests for further details, is a fundamental part of the pharmacist's professional activity.

A commitment that derives directly from the existence of an information asymmetry between health professional and citizen-patient that has certainly not been filled by the availability of an ever increasing amount of data, opinions and communications, through traditional media and even more through the digital ones. Indeed, it is precisely the spread of an enormous amount of information, of which it is difficult to establish source and reliability, that has made this task even more challenging, in particular with regard to complementary medicines, but not exclusively.

In the Pharmacist's Code of Ethics, whose revision was approved on 7th May 2018, Article 6 states that "The pharmacist undertakes to extend their professional competence to unconventional medicines" and in Article 15 it is indicated that "In dispensing, advising and professional counselling, the pharmacist guarantees clear, correct and complete health information, with particular reference to the appropriate use of medicines, their contraindications and interactions, side effects and their preservation".

Merging these two professional obligations requires a constant work of updating, to which this "Guide to Homeopathy" created by SIOMI provides a valuable contribution.

INTRODUCTION

The demand for the use of complementary medicines, in particular homeopathy, is constantly growing. In the 1999 surveys there were more than six million homeopathic drug users in Italy, both adults and children (1). More recent figures suggest that about ten million Italians use homeopathic medicines occasionally or continuously (2). The profile of the homeopathic medicine user in Italy is summarized in Appendix 1. According to ISTAT data published in 2007, in 2005 13.6% of the Italian population, 7 million and 900 thousand people, used unconventional treatment methods and among them the most widespread is homeopathy (7%) (3). Equally significant data arise from similar investigations in the paediatric field (4). For a further update of the use data see the chapter: "Profile of users of homeopathic medicine in Italy" in Appendix 1.

The reasons for the request for complementary treatment methods are several: a common cause is the growing dissatisfaction with conventional therapies and in the way they are used. Both serious and side effects are complained, as is the partial therapeutic efficacy of conventional therapies, particularly in the treatment of chronic conditions such as allergies, headaches, dermatological diseases, etc. The possibility of using homeopathic medicines as well, alongside and complementing traditional medicines, opens up new therapeutic perspectives for many patients (1-4).

The teaching of homeopathic medicine, as well as that of other historical, ethnic and unconventional therapies, is not foreseen by the academic medicine of the western world, although it was for decades in many universities up to a century ago. Therefore, most Italian doctors today do not have a specific knowledge on the subject and are unable to provide adequate advice to patients interested in other treatment methods.

[a] Complementary Medicine otherwise known as Non-Conventional Medicine or CAM (Complementary and Alternative Medicine). With these terms we mean the Medicine that arose alongside modern academic medicine, otherwise called Conventional Medicine, Classical Medicine, Biomedicine. The Council of Europe recognizes seven Complementary Medicines: Acupuncture, Traditional Chinese Medicine, Anthroposophic Medicine, Ayurvedic Medicine, Phytotherapy, Homeopathy, Homotoxicology.

Homeopathic medicine provides a doctor-patient approach that is significantly different from that commonly adopted by the so-called "conventional" medicine and to make the doctor an expert in homeopathy, it is necessary to attend appropriate training schools. It is not considered necessary that all physicians have this type of specific preparation, however they cannot ignore the existence of therapeutic instruments increasingly used by their patients. Being the constant point of reference for their patients, doctors must be able to know the essential features of this widespread treatment system. This Guide was created by the Italian Society of Homeopathy and Integrated Medicine (SIOMI), with the aim of providing information and collaboration to medical colleagues, veterinarians, dentists, pharmacists, and all health professionals so that they can provide patients with specialized advice to make the best choices for them and with them to protect their health.

METHODOLOGICAL FOUNDATIONS OF HOMEOPATHY

Homeopathy, from the Greek *omoios* (similar) and *pathos* (suffering), is a clinical and therapeutic method which consists in treating patients based on the application of the principle of similarity and using medicines at extremely diluted or infinitesimal doses.

HISTORY

Homeopathy was born in the late eighteenth century thanks to the physician, physicist, chemist, and linguist Christian Friederich Samuel Hahnemann. At a time when common medical treatments included blood-letting and poisons, Hahnemann was interested in developing a less aggressive medicine. His thoughts developed following the reading of a text on herbs, learning about the effects of cinchona used for the treatment of malaria. He ingested some "drachmas of good quality cinchona" (5) and observed on himself the development of symptoms which were very similar to those suffered by malaria patients. These symptoms spontaneously regressed, once the intake of cinchona was suspended. This experience led Hahnemann to consider that a substance could cure symptoms identical to those it can produce. This concept, which represents the founding principle of homeopathy, is called the "principle of similarity" or "like cure like". The principle of similarity had been known since the time of Hippocrates, who had noticed, for example, that episodes of recurrent vomiting could be treated with low doses of substances with emetic activity (for example, *Helleborus niger*).

Hahnemann added two further elements to this principle. Once a solution of the homeopathic medicine was prepared, he hypothesized that its efficacy increased through the dynamization of the solution. This dynamization was obtained by applying to each subsequent dilution of the medicinal product a predetermined number of succussions (longitudinal agitations). Another fundamental "turning point" of Hahnemann with respect to the reductionism of the medicine of his time was to consider the patient in a global view and not only from the symptoms of their illness. This is a basic aspect of homeopathic medicine.

The medical examination is aimed at investigating not only the nature of the disease but also its "causality" and its "modalities" and the patient's way of "living" their illness. The term "causality" refers to the environmental, physical and psychological circumstances that may have influenced the onset of the disease. The term "modality" refers to ways of reacting individually to the symptoms of the disease. Another of the keystones of homeopathic medicine is that the symptoms must also be interpreted as the body's attempt to repair its disease: a fever represents the immune response to infection, cough helps the body get rid of mucus. Homeopathic medicines could stimulate the self-healing reaction of the sick body. While homeopathy was spreading throughout Europe by Hahnemann and his followers, Hans Burch Gram imported the homeopathic method into America in 1825. At the end of the nineteenth century, 8% of American doctors also practiced homeopathy and in the USA there were more than 100 homeopathic hospitals and at least twenty homeopathic medicine colleges.

At the beginning of the twentieth century, following the discoveries of Pasteur, with the consequent development of antiseptic therapies and subsequent scientific discoveries, modern western medicine based on allopathic principles (*contraria contrariis curentur*) emerged with an unbridled impulse. In much of the world the use of homeopathic medicine was reduced. In the 60s of the last century this medical thought was reconsidered all over the world and homeopathy is now integrated into the national health service of many countries (eg Germany, the United Kingdom, India, Pakistan, South America, Sri Lanka and Mexico). Currently it is mostly agreed that homeopathy represents a clinical and therapeutic method belonging to medicine and that, as such, should be practiced exclusively by graduates in medicine and surgery, dentistry and veterinary medicine.

KEY CONCEPTS OF HOMEOPATHIC MEDICINE

In homeopathy the methodological assumption is that each individual has an energy called "life force" (5) or "self-healing response". This energy allows the state of health to correspond to a state of equilibrium. The disease originates from a disturbance in the balance of the organism. Homeopathy strives to stimulate the body defence processes and mechanisms to prevent or treat diseases.

The homeopathic treatment is based on the administration of extremely diluted and dynamized doses of substances that produce disease-like symptoms when admi-

nistered in ponderous or toxic doses to healthy individuals. This therapeutic approach is based on the principle: "similia similibus curentur" or "let likes be cured by likes". The homeopathic treatment is personalized to the characteristics of each patient. Homeopaths select the remedies in accordance with a global picture of the patient, considering for each individual not only the symptoms and signs of illness but also the lifestyle, the emotional and behavioural aspects and any other factor useful to frame the whole sick individual. The homeopath therefore treats the sick and not the disease.

Various explanations have been proposed on how and why homeopathy can work. None of these is currently definitively verified.

The results of scientific research in homeopathy appear contradictory in their conclusions. There is evidence demonstrating the therapeutic efficacy of Homeopathy although the mechanism of action of the homeopathic medicine is not yet known. The mechanism of action that foresees opposite effects according to the dose for the same substance can be explained by the phenomenon of hormesis.

The studies of Edward Calabrese (6) show that substances used on biological structures produce opposite effects according to the doses used. At the University of Florence, Department of Chemistry, under the guidance of prof. Andrea Dei and with SIOMI's scientific consultancy, a research project on the application of the hormesis model in the verification of the effect of homeopathic medicines on cellular structures is being implemented. Homeopathy uses an approach to diagnose, classify and treat diseases that is different from those used by modern medicine taught at the Academy.

The principle of similarity, as it has been defined, is based on the assumption that all the medicines used in homeopathy have been previously studied carefully collecting all the elements that emerge in the course of their experimentation on a healthy individual (pathogenesis of the remedy or pathogenetic experimentation) and their clinical and therapeutic use. All these data are also supplemented by the toxicological knowledge already available. Today there are about 1000 substances tested and they come from the plant, animal and mineral world. The knowledge of the experimentations of the substances used in therapy allows the homeopathic doctor to treat with each homeopathic drug patients showing symptoms similar to those produced by single drugs in their pathogenetic experimentation (thus applying the principle of similarity), using them at infinitesimal doses (that is, extremely diluted). The results of the experiments carried out on both healthy and sick humans in over two centuries of investigations are reported in *Materia Medica*.

We can consider the *Materia Medica* as a traditional pharmaceutical handbook (7-9). A tool to achieve the so-called "remedy diagnosis" is also the Homeopathic Matter Repertoire for homeopaths. This tool helps reach the most suitable homeopathic medicine starting from the classification of the collected symptoms then "arranged into a hierarchy" according to their importance and intensity for the patient. In addition to the classic paper tool, modern computerized repertoires are used today.

The mechanism of action of each homeopathic medicine is not known from the perspective of molecular mechanism used by modern pharmacology.

Recent discoveries in the field of immunology could support the hypothesis that the self-healing reaction could take place in a similar way to that usually performed by the immune system in its interaction with a xenobiotic (10). See Chapter 4: "Scientific Research".

It is believed that a homeopathic medicine always produces a self-healing stimulus, as opposed to the inhibitory mechanism (anti-biotic, anti-inflammatory, anti-pyretic, etc.) typical of the conventional drug.

THE HOMEOPATHIC MEDICINAL PRODUCT

The homeopathic medicine consists of infinitesimal doses of a substance of mineral, vegetable or animal origin. Sometimes it is erroneously claimed that homeopathy heals with herbs, creating confusion with other therapeutic practices that have nothing in common with homeopathy, such as herbal medicine, gemmotherapy, the use of herbal infusions or decoctions.

DEFINITION OF HOMEOPATHIC MEDICINAL PRODUCT

In 1995, Italy implemented the Community Directive 92/73/EEC on homeopathic medicines issued in 1992 to harmonize the national regulations on homeopathic medicines and promote their free circulation within the EU. The Legislative Decree 185/95 defined the homeopathic medicine as follows: "Homeopathic medicinal product means any medicinal product obtained from products, substances or compounds, called" homeopathic starting materials ", according to a homeopathic manufacturing process described by the European pharmacopoeia or, in the absence of such description, by the officially used Pharmacopoeias in member states of the EU."

The definition adopted by the Single Code for the Medication in 2006 states: «...any medicine obtained from substances called starting materials for homeopathic preparations or homeopathic strains according to a homeopathic production process described by the European Pharmacopoeia or, in the absence of such description, by the pharmacopoeias officially used in the member states of the EC; a homeopathic medicine may contain more substances".

Recently, the Italian Ministry of Health started a procedure for registering homeopathic medicines carried out by the Italian Drug Agency (AIFA). This registration will end at the end of 2018 extended to the end of 2019. All medicines are prepared from dilutions of the source substance through a series of successive steps codified by the appropriate Official Pharmacopoeias of reference (see Table 1). Homeopathic medicines are described using the Latin name of the sub-

stance of origin followed by an indication of the type and degree of dilution. Ex. *Hypericum perforatum* 9C.

METHODS OF PREPARATION OF HOMEOPATHIC MEDICINAL PRODUCTS

Three methods of preparation are used to prepare homeopathic medicines:

Hahnemanian method

For each dilution, a part of the substance is dissolved in 9 (for decimal dilutions) or 99 (for centesimal dilutions) parts of alcohol at 70°.

Each dilution is followed by a vigorous succussion process called dynamization. The number of succussions is predetermined and reported in the pharmacopoeia. The number of dilutions made constitutes the degree of dilution. The medicines prepared with this method are found on the market defined by the name of the medicine in Latin, the number and type of dilution.

Example

Arnica 2D = second dilution (2) decimal (D)
according to the hahnemanian method (H)

or

Arnica 5C = fifth dilution (5) centesimal (C)
according to the hahnemanian method (H)

Korsakovian method

This preparation technique uses a single bottle filled with the starting substance, and afterwards it is emptied. It is considered that one hundredth of the starting solution remains inside the bottle.

This bottle, used to prepare all subsequent dilutions, is filled with distilled water and the contents are dynamized, obtaining the first Korsakovian dilution.

Subsequently, the method provides for emptying and filling the same bottle again and again, until reaching the penultimate dilution before the desired one, then 70° alcohol is used for the last dilution. The medicines so prepared are defi-

ned by the name of the medicine in Latin, the number and type of dilution, as in the previous method.

Example

Arnica 200K = two hundredth dilution (200)
according to the korsakovian method (K)

Fifty-millesimal dilution method

This preparation technique, minutely described by Hahnemann himself, is quite complex. Subsequent dilutions are obtained by diluting a portion of the substance in fifty thousand parts of solvent (1: 50,000) at each step. The medicines so prepared are found on the market defined by the name of the medicine in Latin, the number and type of dilution, as described in the previous methods.

Example

Arnica 6LM or 6 / 50M = dilution (6) fifty millesimal (LM or 50M)

Homeopathic medicines dispensed in decimal dilutions and in centesimal dilutions up to 12C contain decreasing quantities of molecules of the source substance. In dilutions higher than 12C, finding the molecules of the starting substance is considered unlikely (dilutions higher than Avogadro's number). During this dilution process homeopathic medicines undergo a dynamization at each step, i.e.

TABLE 1 - **Inclusion of homeopathic medicines in official Pharmacopoeias**

COUNTRY	YEAR OF INCLUSION IN PHARMACOPOEIA
■ USA	1938, recognized by the FDA in 1998
■ Europe	1995
■ France	1965
■ India	1971
■ Brazil	1976
■ Germany	1978
■ UK	1993
■ Italy	2002

they are subjected to a shaking process whose intensity and duration are predetermined. Dynamization is considered essential for the effectiveness of the drug.

It is hypothesized that this process is capable of inducing new physical, chemical and/or electromagnetic bonds capable of ensuring the persistence of a therapeutic effect even at ultramolecular dilutions. Much of the criticism to homeopathy focuses on this topic, due to the impossibility to demonstrate the physical-chemical plausibility of extreme dilutions up to now.

See chapter: "Scientific research in homeopathy". Homeopathic medicines are extracted through procedures codified by the main international pharmacopoeias to which pharmaceutical laboratories must comply. In Europe, several national Pharmacopoeias have been recognized and made official (eg Germany,

France, United Kingdom); the American Pharmacopoeia was implemented by the FDA in 1998 (11) (see Table 1). In the fourth edition of the European Pharmacopoeia (2002) a special chapter is dedicated to homeopathic medicines.

PHARMACEUTICAL FORMS

Homeopathic medicines are mainly sold in the form of granules or globules composed of a sucrose and lactose support soaked in the medicinal substance. A granule tube contains from 75 to 140 granules according to the manufacturer. The medicine is taken, in the dilution indicated by the doctor, allowing the number of granules prescribed to be dissolved under the tongue. It is good practice to pour the granules into the tube cap without touching them with your hands.

A tube-dose of globules contains from 200 to 400 globules of smaller size than the granules. The entire contents of this tube must be directly emptied into the mouth, where it is left to dissolve under the tongue. The globule doses offer a greater surface area for absorbing the homeopathic medicine. They are usually prescribed in acute illnesses or when the therapy does not include a daily intake of the medicine. In paediatrics, especially in the case of infants or young children, the medicine can be dissolved in a little water and administered with teaspoons.

There are other pharmaceutical forms on the market, such as eye drops, drops, syrups, suppositories, drinkable phials and injectable vials. The drops consist of solutions in 30% alcohol. Another pharmaceutical formulation consists of the so-called extemporaneous or magistral homeopathic preparations. These are formulas composed of two or more medicines mixed in equal parts (ana parti) prepared in an extemporaneous way, upon specific indication of the homeopathic doctor.

Homeopathic medicines are sold without a prescription with the exception of the preparation of extemporaneous ones. Since the unitary homeopathic medicine treats the individual with the disease and not the disease as such, the prescription of the drug is highly personalized and due to the judgment of the doctor, in relation to the characteristics of the individual patient. The main indications of each homeopathic medicine are reported in homeopathic *Materia Medica*.

There are on the market worldwide some preparations composed of more than one homeopathic medicine, registered as OTC specialties, SOP. These are formulas predetermined by the producers and recommended for the symptomatic treatment of many diseases. In some European countries, such as in France and Belgium, these formulations report the therapeutic indication and the dosage. In Italy the homeopathic medicine has been registered with the status of "homeopathic medicine and therefore lacking recognized therapeutic indications". For this reason on the packaging it is not possible to report any therapeutic, dosage or precautions for use.

The expiration of homeopathic medicines is established by law and is set at five years. The deadline for an extemporaneous formulation is shorter, from a minimum of six months to a year.

The costs of medicines and homeopathic visits can be deducted from the tax return. In Italy, some health insurance companies reimburse both homeopathic visits and the cost of medicines.

SCIENTIFIC RESEARCH IN HOMEOPATHY

INTRODUCTION

Since the early 1990s, Conventional Medicine has adopted the concepts of Evidence Based Medicine (EBM) as a paradigm, which provides indications based on a conventionally valid scientific method based on medical behaviour. It is common opinion that CAM (Complementary and Alternative Medicine), and among them homeopathy, does not have the scientific requirements set by EBM.

Moreover, in recent years Conventional Medicine has been taking again into consideration the utility and limits of EBM; RCTs themselves, although considered the "gold standard" for demonstrating the efficacy of a given therapeutic treatment, are not able to demonstrate its efficacy, that is the real therapeutic utility outside the experimental field. It should also be noted that the therapeutic goal of complementary medicines in general, and homeopathy in particular, is the achievement of the state of health desired by the patient in all its aspects (well-being and quality of life). Therefore the parameters to be considered for the evaluation of their effectiveness are partly different from those used by Classical Medicine (12). Generally speaking, when we want to analyze the issue of scientific research in homeopathy, we need to keep in mind two relevant aspects:

1. **The study method for homeopathic medicines is experimental (pathogenic experimentation)** - Homeopathic medicine has from its origins an experimental approach. In fact, all the substances used in therapy have been tested on healthy humans and their therapeutic power has been verified on the sick. The investigation procedure was standardized by Hahnemann himself who was also concerned with evaluating the effect of placebo (13).
2. **The current scientific methodology is applied with difficulty to homeopathy** - The application to Homeopathy of controlled randomized clinical trials (RCT), considered the "gold standard" for clinical research, requires the resolution of some problems:

Acceptance by the patient - As patients who choose homeopathy pay for this treatment system, they reluctantly accept the possibility of being treated with placebo and not with the active remedy.

Ethical problems - The attitude of bioethics committees is generally unfavourable towards CAM studies, considering them to be prejudicially incorrect based on the hypothetical ineffectiveness of active treatment as well.

Methodological problems - Homeopathy for methodological reasons is far from foreseeing the use of the same remedy in groups of patients suffering from the same symptomatology, since this would entail the absence of an individualization of therapy, an operation that is possible only with exceptionally monomorphic clinical pictures.

Economic problems - The lack of possibility of drug patenting on the market for unitary homeopathic remedies discourages the commitment of companies in developing clinical research protocols. Finally, it should not be forgotten that the worldwide market turnover of homeopathic companies is considerably smaller than that of conventional medicine, representing only 1% of total turnover.

MAIN OBSERVATIONS ON SCIENTIFICITY OF HOMEOPATHY

As noted above, the main objections to homeopathy are about the physical-chemical plausibility of this treatment system. The evidence available as an answer to these objections is set out below. The observations concern three topics: the principle of dilution; the principle of the similarity; the verification of the therapeutic effect.

The Principle of Dilution

As already mentioned, homeopathic medicines are obtained by diluting solutions of substances belonging to the animal, plant or mineral world. With this procedure, after a certain number of dilutions, a measurable quantity of the starting substance is no longer predictable. For the hahnemanian dilution system this occurs after the 12th centesimal dilution. Since a mole (M) of any substance by definition contains 6.023×10^{23} atoms, molecules or ions, a solution of concentration lower than 10^{-24} M (which corresponds to 12C) cannot contain the substance or, better said, the traceable substance.

There are studies shown below which seem to demonstrate (with direct, indirect and clinical tests) the persistence of ultra-diluted solutions.

Direct tests - Some researchers have developed models for evaluating the activity of infinitesimal dilutions. Among these works, the studies by Demangeat deserve attention, showing that the high dilutions of Silicon preserve an activity detectable by Magnetic Resonance techniques (14). We owe other data to Luc Montagnier, with a line of research shared with Italian researchers (Elia, Del Giudice) on the persistence of signals due to viral activities detectable with the NMR technique, even in ultra-thinned dilutions of the virus presence environment (15), partly referring to Benveniste's "water memory" theory (16). An Indian group has documented about various remedies used in homeopathy, how due to characteristics of the solvent-solute interface, after a dilution step lower than 12C, while proceeding to the subsequent steps, the quantity of substance remains unchanged, with measurements using the technique of atomic emission spectroscopy. (17).

Indirect tests - Indirect methodologies have been applied to evaluate the biological effects of infinitesimal dilutions on cellular structures. Poitevin has shown how a 9C dilution of *Apis mellifica*, a medicine obtained through the maceration in alcohol of whole bees, is able to inhibit the degranulation of basophils caused by anti-IgE serum (18). Adopting a similar experimental model, various European research groups, coordinated by Madeleine Ennis, achieved the same inhibiting effect on degranulation by testing histamine dilutions between 7C and 14C (19). Still on cellular models we have apoptosis of neoplastic cells induced with *Ruta graveolens* in the works by Pathak and colleagues (20) or with *Psorinum* on human pulmonary neoplastic cells in the very recent works by Mondal (21). Effects of high dilutions of *Cuprum metallicum* (copper) or *Apis mellifica* on the genic expression of human prostate cells have been demonstrated by the Florentine group of Dei and Dolara (22, 23). The data on human macrophages (24) obtained by Bellavite et others also deal with gene expression, thus suggesting the possibility that homeopathic medicines act by epigenetic mechanisms. Also worthy of mention is the study by Rey which, again using a thermoluminescent technique, obtained results similar to those by Demangeat by studying dilutions of lithium chloride (25).

Clinical trials - There are numerous clinical studies that demonstrate the therapeutic effects of drugs containing active ingredients at infinitesimal dilution. Among the best-known studies, because they are received on international journals of high prestige and particularly remarkable, it is worth mentioning those made by the

group of David Reilly which, since 1987, has published some papers on the efficacy of 30C dilutions of allergens in the control of symptoms in patients with respiratory allergies, asthma and allergic rhinitis (26, 27). The same validity is traceable in Jacobs' works in the treatment of infantile diarrhoea (28, 29). In respiratory diseases are to mention the clinical studies by Colin (30), Launso (31), in ear infections those by Haidvogel (32), Friese (33), Sinha (34) and Jacobs (35). In addition, the 2013 Cochrane dedicated to the effect of Oscilloccinum in the IRR (36) or, in the neurological field, the work by Fibert in ADHD (37) and by Coppola and Montanaro in anxiety and sleep disorders (38).

The Principle of the Similarity

As already explained above, the principle of the similarity is the inspiring principle of Samuel Hahnemann's thought. It states that the symptoms caused by a substance administered in weight doses to a healthy subject (experimental phase) can be treated by administering the same substance in infinitesimal doses (therapeutic phase).

Evidence of the validity of the "Principle of the Similarity" - The assertion of the "similia similibus curentur" has found over time validation from pharmacology, toxicology and, as far as homeopathy is concerned, in the daily clinical practice of numerous doctors and above all in basic and clinical research studies.

The "Similar" in pharmacology and in toxicology - About a century ago Arndt and Schulz stated the law of "inversion of effects" which bears their name and which establishes that "a weak stimulus modestly accelerates the vital activity, a stimulus of average intensity increases it, a strong one depresses it, a very strong one arrests it". The applicability of the Arndt-Shultz law is demonstrated by the significant number of works published on the subject and by the fact that it also represents the model at the basis of the hormesis (22, 23), a term which indicates the phenomenon of the stimulating behaviour of a low-dose substance and its inhibitory or even toxic capacity at high doses.

The fact that this property has been ascertained as a characteristic of over 8000 different substances has led to suggest the existence of a general phenomenon concerning the reactivity of living organisms and not an episodic curious occurrence. For example, low doses of a carcinogenetic element, dioxin, reduce tumours in rats, low doses of a herbicide, phosphone, result in a significant increase in plant growth.

The law of Arndt-Schulz disappeared from the pharmacological texts in the 30s of the last century because it made us assume a pharmacological model that did not foresee a linear dose/response trend of the organism. In addition, it provided an experimental basis to support homeopathy. In the last ten years there has been a lively production of scientific evidences on the subject of hormesis and homeopathy that have encouraged an international debate that has involved Edward Calabrese (the most famous researcher of the phenomenon of hormesis worldwide) who, from being an opponent to the theory that links hormesis to homeopathy, became a supporter of it (he defined himself as the new Schulz).

Beside him, SIOMI has collaborated through the scientific research it has inspired and realized thanks to the activity of the University of Florence with the Department of Chemistry and Pharmacology and with the guarantee of the supervision of the prestigious INSTM (National Interuniversity Consortium for the Materials Science and Technology). This research, begun in 2006 (41), led to the publication of the first work on homeopathic dilution copper in 2010 (22) demonstrating, in the continuation of the research, how the hormetic mechanism is clearly evident also in the works realized with *Apis mellifica* (23, 42).

As a matter of fact, the published works clearly demonstrate, with the DNA microarray technique, an opposite action of the Mother Tincture that stimulates the activity of the gene that encodes the enzyme A2 phospholipase while it is inhibited by dilutions of *Apis mellifica* from 3C to 9C. These data unquestionably demonstrate the hormetic effect of the homeopathic medicinal product (43).

However, among the few international researchers dealing with the DNA microarray technique with homeopathic medicines, there is no agreement regarding the possible explanation of the action of the homeopathic medicine according to a hormetic mechanism (44), although they have discussed on this topic several times internationally (45, 46).

Certainly, anchoring the mechanism of action of the homeopathic medicine to hormesis has the advantage, not a minor one, of including a good part of homeopathy in the new trend of the pharmacology of microdoses accepted by orthodox medicine, removing from homeopathy that slightly magical halo that is given to it due to the theories belonging to the so-called "memory of water".

On the other hand, recent research by the Bellare group, with the help of electron microscopy and electronic diffraction technique and working with homeopathic medicines prepared from metals but not only, have highlighted the constant presence of molecules of the starting substance even in the 200C dilution,

with a concentration that remains constant and around the 6C dilution (47, 48). This phenomenon occurs because in the solutions with a thickness of 0.2 mm the surface is always populated with molecules and always at the same concentration.

Obviously these discoveries are very popular with chemists who do not have to "bear" reasoning such as the concept of the memory of water (49). Just enough to say that the topic is culturally on the way. In any case, the Authors of this Guide want to underline the important turning point that these scientific investigations have given to the evolution of research in homeopathy, since the team of researchers of the University of Florence have started, among the first, the research with the DNA microarray technique in the specific sector of homeopathy.

More generally, although the concept of hormesis has often been ignored at the pharmacological level as a general phenomenon, there are numerous experimental data in the literature that document this behaviour. In these cases, pharmacologists normally indicate the phenomenon as a paradoxical effect and examples of hormesis are mentioned in all pharmacology texts. Initial research on the efficacy of penicillin showed that the antibiotic at a low dose favoured the spread of infection.

In the same way some antihistamines and neuroleptics show a non-linear dose/response trend. Finally, the anti-aggregating effect of aspirin disappears with the dilution to become platelet aggregator at low doses (50).

From these data it seems evident that the foundations of pharmacology developed in the twentieth century should be widely reconsidered.

The "Similar" in homeopathic therapy - After the first experiences of Hahnemann who experimented on himself with cinchona, used in the treatment of malarial fevers, obtaining a picture of symptoms similar to that of the patients in which cinchona was used therapeutically, the principle of similarity has been verified in the experimentation of all the substances used then as homeopathic medicines. The applicability of the principle of similarity is demonstrated in some RCTs (see Table 3).

Verification of the therapeutic effect of the homeopathic medicine

The criticisms regarding the possible therapeutic effect of the homeopathic medicine are particularly emphasized by its detractors, who argue that there is no demonstration of how an infinitesimally diluted substance can have therapeutic effects. On the other hand it is known that the problem of incomplete knowledge of the mechanism of action has existed also in the use of several so-called conven-

tional drugs at least in the first phase of their use (for example, the Immunoglobulins administered intravenously in case of some autoimmune diseases, the specific immunotherapy of respiratory allergies, Aspirin itself, etc.) and of many drugs, the therapeutic indication was found in pathologies other than those for which they had been studied (serendipity).

In an attempt to explain the action of ultramolecular dilutions of substances (compatible with those used in Homeopathy) scientific works and theories have been produced that imply both the so-called "memory of water" and phenomena of fluctuation, and models commonly called "electromagnetic coherence domains" (51). We have also already mentioned the works by Dei and Bellavite on genic expression, which could lead to hypothesize epigenetic effects for homeopathic drugs. It is also conceptually acceptable that the mechanism of action may be different depending on the case. Nowadays, however, there are no definitively accepted data on the subject. It is our opinion that it would be advisable to carry out differentiated studies to investigate the effect of molecular and ultramolecular dilutions of homeopathic medicines. By consulting the Medline database there are numerous works on homeopathy, including several meta-analyses. A comment is appropriate for meta-analyses, considering that they are at the top of the hierarchy of effectiveness tests.

Recently, unfavourable meta-analyses have appeared against homeopathy. The first, signed by Shang (52), concludes that there is little evidence for a specific effect of homeopathic remedies, but it is based on the evaluation of only eight works without providing any details and yet soliciting great criticism for the methodological approach (53). The most recent is the meta-analysis conducted by the Australian National Health and Medical Research Council (54) which states that there are no clinical situations among those examined in which homeopathy shows to have effect, using a questionable method according to which if there are evidences that prove the effectiveness of homeopathy in a certain pathology they are cancelled by the works that deny it, also omitting among other things some significant meta-analyses with positive results in specific pathologies such as those of Jacobs in infantile diarrhoea (28), by Wiesenauer in pollinosis (55) and by Schneider in vertigo (56). Other meta-analyses with favourable results should be noted, cumulating the data obtained in all clinical conditions such as, in chronological order, that by Linde and others (57), Klejinen (58) and, more recently, Mathie (59).

TABLE 3 - **Randomized clinical trials (RCT)**

AUTHORS	STUDY	CONCLUSION
■ Coppola et al. <i>2013 Homeopathy</i>	Open-label, observational, open retrospective study, 71 subjects	The treatment of anxiety and sleep disorders with Datif-PC® is able to produce remarkable improvements also in a short period of time.
■ Sinha et al. <i>2012 Homeopathy</i>	Pilot study, randomized controlled trial with placebo. 81 patients	Individualized homeopathy it is an effective treatment in acute otitis media (AOM)
■ Mathie et al. <i>2012 Cochrane Database Syst Rev</i>	Randomized trials, controlled with placebo of Oscillocochinum® in prevention and/or treatment of flu and flu-like disease in adults or children. Six studies included.	There is not enough evidence on the effectiveness of Oscillocochinum® in the prevention or in the treatment of influenza and flu-like illness.
■ Haidvogel et al. <i>2007 BMC Compl Alt Med</i>	Multicenter non-randomized cohort study. 1,577 patients (857 homeopathy and 720 conventional).	The homeopathic treatment for respiratory disorders and acute otitis has the same effectiveness of conventional treatment.
■ Jacobs et al. <i>2007 Homeopathy</i>	Randomized, double-blind study, 60 patients	Homeopathic therapy not effective for symptoms of Dengue fever
■ Colin et al. <i>2006 Homeopathy</i>	Observational study 147 patients	The success rate of homeopathic treatment is 87.6%.
■ Launsø et al. <i>2006 Homeopathy</i>	Retrospective study, 88 patients	Patients have a clinical improvement.

TABLE 3 - **Randomized clinical trials (RCT)**

AUTHORS	STUDY	CONCLUSION
■ Brinkhaus et al. <i>2006 Compl Ther Med</i>	Randomized, double-blind study, 227 patients	Arnica montana proves to be effective in reducing knee surgery post-intervention symptoms
■ Frei et al. <i>2005 Eur J Ped</i>	Randomized double-blind study controlled with crossover placebo. 83 children	The study suggests scientific evidence of the effectiveness of homeopathy in the treatment of attention deficit disorder.
■ Pathak et al. <i>2003 Int J Oncol</i>	Controlled, 15 patients	Ruta graveolens effective in the brain tumour therapy
■ Lewit et al. <i>2002 BMJ</i>	Randomized, double-blind study, placebo, 60 patients	Homeopathic oral treatment in asthmatic patients allergic to house dust shows differences over placebo
■ Oberbaum et al. <i>2001 Cancer</i>	Randomized, double-blind study, placebo, 32 children and 30 checks	A homeopathic complex (Traumeel®) reduces the severity of pain and inflammation of the oral mucosa in children on chemotherapy
■ Jacobs et al. <i>2001 Ped Infect Dis</i>	Preliminary randomized study, controlled with placebo. 75 patients	These results suggest a positive effect of homeopathy compared to placebo in the treatment of acute otitis media.
■ Taylor et al. <i>2000 BMJ</i>	51 participants and 50 checks	A homeopathic preparation oral for allergic rhinitis significantly reduces symptoms compared to placebo
■ Jacobs et al. <i>2000 Pediatrics</i>	126 children treated by comparison with 116 children with placebo	An individualized homeopathic treatment highlights a therapeutic superiority compared to placebo

TABLE 3 - **Randomized clinical trials (RCT)**

AUTHORS	STUDY	CONCLUSION
■ Rastogi et al. <i>1999 BHJ</i>	100 HIV-positive patients	The homeopathic treatment improves the level of CD4 only in the group of patients treated, not in the placebo group
■ Weiser et al. <i>1998 Arch Otor Epid</i>	119 patients and 105 control patients	A homeopathic medicine has the same effectiveness as the conventional treatment in reducing the intensity and duration of vertigo attacks
■ Friese et al. <i>1997 Int J Clin Pharmacol</i>	Prospective observational study. 103 children in group A (homeopathic therapy) 28 children in group B (conventional therapy)	Of the children treated with homeopathic therapy, 70.7% were relapse free within a year and 29.3% had a maximum of 3 relapses. In the group treated with conventional therapy 56.5% were free of relapses while 43.5% had a maximum of 6 relapses.

TABLE 4 - **Meta-analysis**

AUTHORS	STUDY	CONCLUSION
■ Mathie et al. <i>2014 Systematic Reviews</i>	Homeopathic therapy including 22 trials	In favour, although other trials are needed to be able to confirm this data
■ Peckam et al. <i>2013 Cochrane Database Syst Rev</i>	Homeopathic therapy, including 3 trials with 213 participants	In favour
■ Meyer et al. <i>2013 European Journal of Medical Sciences</i>	Homeopathy, acupuncture and phytotherapy, 135 reviews	Scarcely evaluable data, need for further research
■ Optum <i>2013 NHMRC Homeo Working Committee</i>	Homeopathic therapy 57 reviews	Scarcely evaluable data to demonstrate the effectiveness of homeopathy
■ Shang et al. <i>2005 Lancet</i>	Homeopathic therapy	Against, not different from placebo
■ Ernst <i>2002 Br J Clin Pharm</i>	Homeopathic therapy 11 publications	Non-evaluable data
■ Jonas <i>2001 Compl Alt Med</i>	Homeopathic therapy 59 publications	Poor methodology
■ Linde <i>2000 Int j Epidemiol</i>	Homeopathy, acupuncture and phytotherapy 207 publications	Poor methodology
■ Cucherat <i>2000 Eur J Clin Pharm</i>	Homeopathic therapy 24 publications	In favour, other than placebo
■ Linde <i>1997 Lancet</i>	Homeopathic therapy 186 publications	In favour, other than placebo
■ Klineen <i>1991 BMJ</i>	Homeopathic therapy 105 publications	In favour

FIELD OF APPLICATION AND USE LIMITS

The homeopathic treatment is not able to promote any kind of therapeutic effect in clinical situations where it is not possible to start a natural healing process. For this reason it cannot be used to repair lost functions such as that of the nervous system, to restore missing hormones or for diseases for which a mandatory surgical operation is required.

As a palliative treatment, it can help improve living conditions in many diseases (eg, damage from chemotherapy drugs) (60).

In general, homeopathy can be used for the treatment of both acute and chronic diseases in the following cases:

- the doctor does not consider other treatments taken into consideration as satisfactory;
- the doctor and/or patient want to reduce the use of drugs for long-term treatments and/or want to verify some therapeutic alternatives to treatments that are considered too invasive with respect to guarantees of therapeutic efficacy;
- the patient cannot use conventional drugs for intolerances, allergies, serious side effects, etc.
- the patient, adequately informed about risks and benefits, requests it as a preferential treatment.

The field of application of homeopathic medicine is, according to the experience of homeopathic doctors, consistent with the statements made by the patients who use it both in the 1999 and 2004 Doxa surveys (see Table 5) (1, 2) and in the survey exclusively related to the paediatric population (see Table 6) (4). In the ISTAT survey published in 2007 (3) 71.3% of patients who used homeopathy declared themselves satisfied with the results obtained while 21.9% reported only partial benefits.

TABLE 5 - **Diseases treated with homeopathic medicine in all age groups**

DISEASE	PERCENTAGE
■ Recurrent respiratory infections	29%
■ Anxiety, insomnia, depression	18%
■ Gastrointestinal disorders	18%
■ Bone and muscle pains	12%
■ Allergies	11%
■ Dermatological diseases	8%
■ Circulatory problems	8%
■ Gynaecological problems	8%
■ To lose weight	5%
■ As a tonic treatment	6%
■ As an anti-inflammatory remedy	5%
■ For other disorders and problems	13%
■ Unspecified pains	3%

Survey of 6024 families (Doxa, 1999) and of 1005 families (Doxa, 2004).
On average 1.5 disorders were indicated per interviewee.

TABLE 6 - **Main diseases treated with homeopathic medicine in paediatrics**

DISEASE	PERCENTAGE
■ ENT infections	33%
■ Allergies	12%
■ Dermatological diseases	10%
■ Sleep disorders	9%
■ Lung diseases	8%
■ Gastrointestinal diseases	7%
■ Eating disorders	4%

Survey carried out on 3750 families. Trapani, on a paediatric population.

ADVERSE EFFECTS OF HOMEOPATHIC THERAPY

The adverse effects of the homeopathic therapy recorded in clinical trials were mainly related to temporary aggravations of the symptoms being treated or the appearance of transient and minor effects: headache, asthenia, rash, dizziness, diarrhoea (61). Even the FDA, after evaluating the data concerning the hypothesis of adverse effects due to homeopathic medicines, concludes that these medicines cannot cause adverse effects due to their high dilution (61). Certainly, even in the molecular dilutions (lower than 12CH) the concentration of molecules of the source substance is so scarce that it cannot cause toxic effects.

The accidental ingestion of an entire tube of granules of any homeopathic medicine does not involve the adoption of any anti-poison procedure.

When we want to evaluate the adverse effects of a homeopathic medicine, we must distinguish between **direct** risks (attributable to the medicine itself) and **indirect** risks (to be attributed to errors in the therapeutic choice by the operator).

Undoubtedly the greatest risks associated with homeopathic therapy are to be attributed to indirect risks. For this reason it is necessary to affirm that all the institutions involved in the training and diffusion of homeopathy must do their utmost to ensure that the exercise of homeopathic medicine and the prescription of homeopathic medicines are the exclusive responsibility of doctors graduated in medicine and surgery, dentists and veterinarians doctors. This suggestion was also expressed by the FNOMCeO (National Federation of Associations of Physicians and Dentists) itself in the 2002 Terni resolution. It is also essential that the physician expert in homeopathy uses all the diagnostic tools used in modern Western medicine in order to make a correct diagnosis of the disease. Any therapeutic choice must result in the diagnosis and careful assessment of the risks and benefits of both systems of healthcare and provide for the acquisition of informed consent. The deontological aspects of the professional practice of the doctor experienced in homeopathy were for the first time defined by the same homeopathic doctors in the document prepared by SIOMI "Recommendations for the Practice of Homeopathy in Integrated Medicine" and delivered to the FNOM in 2004 (62).

In general, it is possible to state that:

- Homeopathic medicines taken in high dilutions and under the supervision of a doctor are not able to determine **toxic effects** (61). This statement is also valid in the case of accidental ingestion of an overdose of medicine. However, it is always advisable to inform the homeopathic doctor of the occurrence.
- The **worsening symptoms** that can occur sometimes in the early days of a homeopathic therapy are interpreted as the body's attempt to restore health. These symptoms, which constitute the so-called *homeopathic aggravation*, are reversible within a few days. If these symptoms do not regress, it is very important to reassess the diagnosis of the disease and the possibility that they will reveal an ongoing aggravation of the pathology due to reasons dependent on the disease itself.
Liquid homeopathic medicines contain alcohol. Although the doses taken are irrelevant (10-20 drops per dose of homeopathic medicine dispensed with 30% alcohol titration) some patients may feel burning and discomfort. In these cases, it is advisable to change the pharmaceutical formulation or dilute the medicine in a greater quantity of water.
- There is no evidence that homeopathic medicines **can interfere with conventional drugs** (61). It is a good rule, however, when possible, to take homeopathic medicines at different times of the day compared to some conventional drugs (cortisone, antihistamine, hormones, chemotherapy). It is however necessary for the patient to fully inform both their own doctor and homeopath about the treatment they are following.
- Homeopathic medicines are not contraindicated during pregnancy. The common experience of homeopathic doctors is that there are no side effects. However, patients should be advised to notify their homeopathic doctor as soon as they know they are pregnant.
- The problem concerning the intake of homeopathic remedies by lactose intolerant or celiac disease patients has been raised: the amount of lactose contained in the granules is so low that it does not cause symptoms; however, if these occur in subjects with absolute lactase deficiency, the remedies can be prescribed in the drop formulation. There are no reasons related to the preparation techniques that justify the presence of gluten in the products.

Homeopathic medicines require a variable reaction time according to the individual and the pathology treated. However, waiting times for a response to homeopathic treatment must be reasonably short. In general, in acute pathology the therapeutic response must be visible within a few hours up to a maximum of two days. In chronic diseases, it can sometimes wait up to a couple of months for a detectable and consolidated improvement.

DEONTOLOGICAL ASPECTS OF THE HOMEOPATHIC MEDICINE PROFESSIONAL PRACTICE

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Although it may seem theoretically paradoxical, the Order of Physicians, at least in its current framework, is an institution that essentially protects the citizen. From the Order the doctor is protected only indirectly, and above all with a series of rules and warnings, rather than reassurances or promises.

What the citizen must know, however, is that the Order considers all doctors as equal, without any distinction: the Order is for all doctors and not for a part of them. For this reason it should not be surprising that the Code of Medical Ethics, even in its last draft, devotes an entire article (15) to "Unconventional systems and methods of prevention, diagnosis and treatment", despite the various opinions in this regard are still largely conflicting and, in many cases, even opposed.

Already from the first paragraph of the article it is evident that the main purpose of the Order, and therefore of the doctor protected by this body, must be the decorum and dignity of the profession in this area itself. Any medical activity of the doctor's competence, even if it has some aspects that are different from the traditional canons, will always have to respect that code of correctness and nobility that has always conferred to the medical act an aura of almost sacredness ... The bioethical principle of beneficence will therefore be maintained even among the complementary medicines as it is in the case of traditional medicine: it will not therefore be a question of competing between supporters of a current or another, nor of having interests of any kind prevail.

For this reason, the citizen who uses the services of a doctor must know that that doctor will undertake to treat him in the best possible way in the context of their specific skills and conscience as a professional and as a human being.

His knowledge in an unconventional context must therefore be seen as an extra possibility that the doctor can offer to their patient, and not as an obligatory alternative to traditional treatments, perhaps based on a particular philosophy. The second and third paragraphs of the same article, when specific and scientifically consolidated treatments are highlighted, place in any case the scientifically proven therapies at a higher level than others that until now have not availed themselves of studies of proven efficacy, so as the evidence based medicine hopes: this should not lead the reader to see an error in the enunciation of the first paragraph, considering a formality the quotation of the unconventional systems and methods of prevention, diagnosis and treatment to these conditions.

This is not an error or an easy persuasion from the commission for the drafting of the Code of Ethics. It is well known that the funds available to traditional medicine, in particular the pharmacological one, have always been greater than the budgets established for non-conventional medicines (up to now, however, excluded from the national health plan). It is also known that some complementary disciplines (in particular homeopathy) require very specific parameters, based above all on the rule of *hic et nunc* (that cure for that patient at a given time), for which the traditional scientific method may not be sufficient (because set to large samples).

There is no doubt, however, that if the methods of epidemiological investigation were revised even in the light of unconventional medicines, or whether the scientific works on the subject of unconventional medicine were considered sufficient and therefore accepted, the same unconventional systems and methods would *ipso facto* be included into the category of "treatments with proven efficacy".

To protect the citizen, but also the doctor and medicine, there is still a tool that favours the doctor-patient relationship even in these areas: we refer to the informed consent, indeed "explicit and informed", also indicated by Article 15, but described in full in Article 35 of the aforementioned Code.

The doctor must always put their patient in a position to know the procedure he will undergo, especially if the doctor believes that there may be risks.

By making him read and sign the informed consent form, the doctor must provide the patient with "the most appropriate information on the diagnosis, prognosis, perspectives and possible diagnostic-therapeutic alternatives and on the foreseeable consequences of the choices made; the doctor will have to communicate with the subject, taking into account their understanding skills, in order to

promote maximum participation in the decision-making process and adherence to diagnostic-therapeutic proposals"(art. 33).

This article is not written or designed for non-conventional medicines, but should be extended to them, regardless of whether for some they are harmless medicines or, as they are mistakenly called, "sweet". Also in this case the Order adopts a vision equal to all the medicines, convinced that there are not so many medicines, but only one medicine. On the fourth paragraph there seems to be no apparent doubt: the doctor cannot and must not collaborate in any capacity or favour the exercise of non-medical third parties in the field of unconventional systems, methods of prevention, diagnosis and treatment (which would undermine the decorum and dignity of the profession).

The clarification «in the non-conventional disciplines recognized as exclusive activities typical of the medical profession» is more than ever appropriate, as in the non-conventional disciplines it is easier to recall easy money, perhaps even at the expense (it must be said!) of the citizen who is frequently unaware of what is done or given, encouraged to ask for special services because they are sold as "natural" or "non-toxic". It may therefore happen that this type of economic or thaumaturgical mirage can in some cases also induce a graduate in medicine to lend his name to initiatives that have nothing to do with a doctor, or to cover for non-doctors to perform medical activities.

Here the Order is preemptory, to the point that - as stated in Article 67 of the Code of Medical Ethics - it will have to be informed of who carries out an unauthorized practice of the profession. Not only that, the doctor who realizes such an offense, will have to indicate the names and surnames of the non-doctors, but also of the doctors, to the professional order that will first check and then, if there will be confirmation, will take the appropriate measures within its authority.

From a closer observation, these first references of the Code of Conduct to non-conventional disciplines start above all from the real risk of the abuse of the profession, connected on the one hand to economic advantages, but perhaps also linked to occupational shortages, especially of young medical graduates who can fall into easy temptations at the beginning of a career which, however, they run the risk of dropping.

The other aspect that is certainly no less important is that the Order of Physicians gives great trust to serious doctors who respect their professional ethics, not preventing them from studying and practicing new ways of doing medicine, but always basing themselves on the "fundamentals" of the field, acqui-

red in the university environment, and aimed at the full well-being of the patient. It is no coincidence, and it is known with pleasure, that in the last draft of the Code of Medical Ethics the phrase *unconventional practices* has been eliminated and replaced with *unconventional disciplines*, giving to the sole doctor the task of using them to the best for the good of the patient.

CODE OF ETHICS

ART. 15 - NON CONVENTIONAL SYSTEMS AND METHODS OF PREVENTION, DIAGNOSIS AND TREATMENT

The doctor can prescribe and adopt, under their direct responsibility, unconventional systems and methods of prevention, diagnosis and treatment in respect of the decorum and dignity of the profession. The doctor must not distance the person being treated from scientifically based treatments of proven effectiveness.

The doctor guarantees both the quality of their specific training in the use of unconventional systems and methods, and a detailed information for acquiring consent. The doctor must not cooperate or favour the practice of non-medical third parties in non-conventional disciplines recognized as exclusive activities reserved to the medical profession.

ART. 33 - INFORMATION AND COMMUNICATION WITH THE PATIENT

The doctor guarantees the patient or their legal representative comprehensible and comprehensive information on prevention, diagnostic path, diagnosis, prognosis, therapy and any diagnostic-therapeutic alternatives, predictable risks and complications, as well as behaviour that the patient will have to observe in the healing process.

The doctor adapts the communication to the capacity of understanding of the patient or their legal representative, corresponding to each request for clarification, taking into account the sensitivity and emotional responsiveness of the same, in particular in the case of serious or unfortunate prognosis, without excluding elements of hope. The doctor respects the necessary confidentiality of the information and the willingness of the patient not to be informed or to delegate the information to another person, reporting it in the health documentation.

The doctor guarantees to the minor elements of useful information so that they understands their health condition and the programmed diagnostic-therapeutic actions, in order to involve them in the decision-making process.

Art. 35 - INFORMED CONSENT AND DISSENT

The acquisition of consent or dissent is an act of specific and exclusive competence of the doctor, which cannot be delegated. The doctor does not undertake or goes on with diagnostic procedures and/or therapeutic actions without the prior acquisition of informed consent or in the presence of informed dissent. The doctor acquires, in written and signed form or with other modalities of equal documentary efficacy, the consent or dissent of the patient, in the cases provided for by the law and by the Code and in those expected to be burdened by a high risk of mortality or by results affecting significantly on psychological and/or physical integrity. The doctor takes into due consideration the opinions expressed by the minor in all the decision-making processes that concern them.

ART. 67 - NOMINEE AND SUPPORT FOR THE UNAUTHORIZED PRACTICE OF THE PROFESSION

The doctor is forbidden to collaborate with any right or to favour, by acting as a nominee or omitting due vigilance, whoever exercises the profession illegally. The doctor who becomes aware of services performed by those who are not authorized to practice as physicians, or cases of abusive behaviour, is obliged to report them to the territorially competent Order.

COST-BENEFIT RATIO IN HOMEOPATHY

Homeopathic medicine is relatively inexpensive and experience suggests that the health potential it generates is able to decrease drug consumption and healthcare services. This aspect implies interesting perspectives in the field of drug-economy.

Over the last forty years, in all the industrialized European countries, GDP-related health expenditure has steadily increased. The need to adopt a new model for the management of chronic diseases, whose therapeutic costs have a significant weight in terms of pharmaceutical expenditure, is widely supported.

In Italy it is estimated that chronic patients are over 17 million. In most chronic diseases homeopathic therapies can represent a valid opportunity. In particular, the chronic patient represents a field in which it is possible to intervene therapeutically also with homeopathic medicine in the management of pathologies or syndromes of broad social cost, such as allergic rhinitis (63), otitis (34, 35, 64) and benign chronic pain (65). It is interesting to note the results of studies conducted in Europe (65, 66) which compared the prescriptive costs of homeopathic general practitioners with those of conventional general ones.

Homeopathic general practitioners, resorting less to the prescription above all of antibiotics, anti-inflammatories and painkillers, have registered a statistically prescriptive expenditure of 20-50% less than their conventional colleagues.

There are not many definitive data regarding the cost-effectiveness ratio of homeopathic therapies since large-scale economic evaluations were not carried out due to the lack of money to be allocated to this kind of research.

However, some studies have shown that the cost for the purchase of conventional drugs and for medical examinations decreases after the introduction of homeopathy (67). Several papers in international literature have been published on this topic (66-68). The study by Claudia Witt and colleagues in 2005 examined the results and costs of complementary treatments in Germany by observing, in groups of patients with comparable clinical characteristics, that subjects treated by general practitioners who prescribed homeopathic medicines had better clinical results on an equal basis cost (65).

A more recent study is the work published in the *European Journal of Health Economics* (69) which explored the cost-benefit ratio of Complementary Medicine (CM) compared to official medicine, comparing the databases of 1,913 conventional doctors with those of 25 doctors also experts in acupuncture, 28 doctors experienced in homeopathy and 26 in anthroposophy. The result reported is that the patients of doctors trained in CM also spend up to 30% less in health centres and classic medical care and live up to 30% longer. The cost reduction was related to shorter hospitalizations and less use of prescription drugs. Some of these studies, carried out in Europe, have compared the costs of prescriptions made by homeopathic doctors with those of general practitioners.

For example, a survey of 500 patients treated at the Royal London Homeopathic Hospital (66) evaluated the consumption of conventional drugs before and after homeopathic treatment and found that 29% of the patients taken into account suspended them after homeopathic treatment, 32% reduced them, 33% continued to use the same amount while only 6% increased consumption.

The major benefits of homeopathic care have been reported for musculoskeletal disorders, dermatology, pediatrics, genito-urinary tract, neurological and respiratory diseases. A study carried out in England on 100 patients assisted by a general practitioner followed for four years, compared the expenditure on both homeopathic and conventional drugs. The cost of the homeopathic medicines purchased and the cost of conventional drugs that would have been prescribed for these patients, have been calculated for the whole period. The savings were calculated at 100 euros per patient. The majority of patients enjoyed a better state of health and none of them reported side effects (66).

These data seem to be particularly significant, and numerous governments, in Europe and in other parts of the world, have recently chosen to allocate funds for research into the usefulness of Complementary Medicine.

HOMEOPATHY AND THE OPINION OF ITALIAN AND INTERNATIONAL INSTITUTIONS

The FNOMCeO has recognized the practice of non-conventional/complementary medicines as the exclusive competence of the doctor with the resolution of the National Council held in Terni in May 2002. The Italian government for several legislatures has been committing to a project for the setting of rules on the subject.

In Europe, the European Parliament resolution of May 1997 highlights the "need to guarantee citizens the widest possible freedom of therapeutic choice, ensuring them the highest level of safety and the most correct information on harmlessness, quality, the effectiveness of these medicines".

In a subsequent resolution of the Council of Europe (no. 1206, of 1999) the Member States are again invited to regulate the status of these medicines in order to be able to include them fully into the National Health System. These resolutions follow the 1992 Community Directive (Dir. EEC 92/73 and 92/74) which intended to favour the free circulation of homeopathic medicines within the Community, guarantee access to treatment by patients and offer quality guarantees and product safety, and in any case provide for a simplified procedure for placing these drugs on the market.

Finally, it should be noted that the resolution of the European Parliament on the statute of non-conventional Medicine No. 400 75/97 of May 1997 invites the Member States to "give information on these medicines, suggesting that the preparation of graduates in medicine and surgery includes also an initiation to certain unconventional disciplines".

The position of the European institutions towards homeopathy is summarized in Table 7.

Recently in Italy, following the presentation of a draft law that should regulate complementary medicines in our country, the National Bioethics Committee (NBC), an advisory body to the Italian Parliament, has spoken out against these medicines. In a document entitled "Alternative medicines and the problem of informed consent" (71), released in March 2005, the NBC itself reiterated the formal condemnation of the practice of medicines other than the academic one.

In the document, among other things, the use of homeopathy for children is not recommended. It is very interesting to note that, although the document contains the unanimous consent of all members of the Committee, some members considered it necessary to make interesting distinctions attached to the document in some personal notes. In particular: "...The theoretical bases and the explanation of the mechanism of action of the treatments are the guide of the medical practice, but their lack does not exclude the recourse to treatments documented in an irreproachable way from the point of view of efficacy and safety. It should be noted, moreover, that many drugs of modern scientific medicine have been introduced into therapy without knowing the mechanism of action ...".

"On the basis of these principles, codified by the so-called 'evidence medicine', it is believed that alternative or non-conventional medicine should be judged primarily on the basis of documentation, provided with methodologically correct criteria, of the efficacy and safety of care. ... In conclusion, it seems as shareable the opinion of the Director of the Complementary and Alternative Medicine Centre of the NIH-National Institutes Health, according to which alternative or unconventional medicines offer several interesting opportunities, which should be evaluated in an "appropriate manner", where the term "appropriate" refers to the respect for the scientific method". For completeness of information, some examples are given below regarding the situation of homeopathy in institutions of non-European states (78).

America

United States - Homeopathic medicines have been made official since 1938 and regulated by the FDA. Homeopathy is taught in many universities and it is interesting to note that a special commission appointed for this purpose by the NIH (National Institute of Health of the United States of America) has published a recommendation that the Secretariat of the US Department of Health and Humans Services supports research for the supply of integrated care and facilitate the identification of infrastructures in which it is possible to favour the development of professional courses for those doctors who want to devote themselves to integrated medical care. The most significant initiative was taken in 2004 with the creation of the "Consortium of Academic Health Centers for Integrative Medicine" which up to now has aggregated 72 university offices with the aim of promoting a rigorous research activity on the possibilities of applying the integration between Conventional Medicine and CAM (72).

Brazil - Homeopathy has been recognized as a medical specialty since 1980 by the Conselho Federal de Medicina.

Mexico - Officially recognized.

Africa

In Ivory Coast, Senegal, Kenya, Nigeria, the exercise of homeopathy is an exclusive practice of medical doctors and is present in many clinics and religious missions.

Asia

India - Homeopathy is registered with the NHS alongside Western medicine and the two systems of Indian medicine (Ayurveda and Unani). There are more than 250,000 homeopathic doctors who have followed a training path defined by the Ministry of Health, through the AYUSH Department, whose acronym is the result of the initials of five major systems: Ayurveda, Yoga, Unani, Siddha and Homeopathy.

Pakistan - Out of 10,000 registered doctors in Pakistan, around 5,000 regularly use homeopathy and homeopathic medicines are reimbursed by the NHS.

Table 7 shows the European regulations concerning homeopathic medicines, their regulation, their possible partial or total reimbursement by the NHS, as well as the recognition of the qualification of doctors.

TABLE 7 - **Officialization of homeopathy in Europe**

COUNTRY	STATUS OF HOMEOPATHY	PROFESSIONAL STATUS	STATUS OF MEDICINAL PRODUCT
■ AUSTRIA	Recognized as a specialty by the Medical Orders		Regulated as medicines and reimbursed by the NHS and by many private insurance
■ BELGIUM	Recognized in 1999		Regulated as medicines and reimbursed partly by the NHS and by many private insurance companies
■ DENMARK			Regulated as medicines
■ FINLAND			Regulated as medicines and reimbursed by the NHS if prescribed by doctors

TABLE 7 - **Officialization of homeopathy in Europe**

COUNTRY	STATUS OF HOMEOPATHY	PROFESSIONAL STATUS	STATUS OF MEDICINAL PRODUCT
FRANCE		"Doctors with a homeopathic orientation" is the qualification recognized to doctors who have attended a post-graduate course	Regulated as medicinal and partly reimbursed by both the NHS and by private insurance companies when prescribed by doctors
GERMANY		The title of "homeopathic doctor" is recognized by the Medical Orders	Regulated as medicines and reimbursed by health insurance funds
IRELAND			Regulated as medicines and reimbursed by the NHS
GREECE			Regulated as medicines
ITALY			Regulated as medicines and reimbursed by some private insurance companies
LATVIA	Recognized as a medical specialty		Homeopathic visit reimbursed
LIECHTENSTEIN			The services provided by qualified doctors are reimbursed by health insurance funds
LUXEMBOURG			The services performed by qualified doctors are reimbursed
NETHERLANDS		The title of "homeopathic doctor" is recognized by medical societies and professional associations	Regulated as medicines and reimbursed by the NHS and by private insurance companies
PORTUGAL	Officially recognized in 2000		
UK			Regulated as medicines and reimbursed by the NHS if prescribed by affiliated doctors and by some private insurance companies
RUSSIA	Recognized as a medical specialty		Their use is permitted in every hospital and clinic

TABLE 7 - **Officialization of homeopathy in Europe**

COUNTRY	STATUS OF HOMEOPATHY	PROFESSIONAL STATUS	STATUS OF MEDICINAL PRODUCT
■ SPAIN			Regulated as medicines and reimbursed by some private insurance companies
■ SWEDEN			Regulated as medicines
■ SVIZZERA	Recognized in 2012		Reimbursed by the NHS as long as prescribed by doctors with specific post-graduate training
■ UKRAINE			Regulated as medicines
■ HUNGARY	Recognized in 1997		

TRAINING IN HOMEOPATHIC MEDICINE

On May 18th, 2002, the FNOMCeO (National Federation of Orders of Physicians and Dentists) published "The FNOMCeO guidelines on unconventional medicines and practices" recognizing nine disciplines under the exclusive jurisdiction of graduates in Medicine and Dentistry, including homeopathy. In 2010 the FNOMCeO published the recommendations on the education and training criteria in Complementary Medicine (CM): number of hours of basic courses, number of years, training programs, qualifications for teachers of these courses, etc.

The interregional technical committee for the CM (whose direction was assigned in 2007 to the Tuscany Region) was set up to define the national criteria for CM education and training, reaching an agreement that in February 2013 was also implemented at a national level; these rules relating to training in homeopathy (which also concern other CM: acupuncture, phytotherapy, homotoxicology and anthroposophic medicine) currently only involve doctors and dentists and also include accreditation criteria in the professional orders of doctors who practice CM. It is expected that it will also be extended to pharmacists and veterinarians. Even the Universities, after the document signed by the Conference of Deans and Presidents of the degree courses in Medicine and Surgery in Alghero in 2004 ("Complementary medicines and degree courses in the health area"), have adapted their offer by creating Specialization and Master Courses on the main CM at numerous faculties (Florence, Siena, Rome, Milan, Messina, etc.), while various universities have activated elective courses before graduation to provide students with general information on the sector.

In July 2014, the Ministry of Health issued a "Clarification note" concerning the application of the agreement signed in February 2013 between the Government, Regions and Autonomous Provinces of Trento and Bolzano concerning the training and practice of the CM. The ministerial note was the necessary complement to ensure a correct and homogeneous application throughout the national territory of the agreement which, for the first time in Italy, defined the criteria and methods of training for professionals in complementary medicines; it contributed

to a greater interpretative clarity of those regulatory aspects which in the agreement, for obvious reasons of political expediency, proved too general and therefore required more details and specific definitions and further contributed to amalgamating the training paths.

These principles, reaffirmed precisely in the explanatory note of the Ministry, back up the need to proceed with the quality certification of the training in acupuncture, phytotherapy, homeopathy, including homotoxicology and anthroposophic medicine, identifying minimum and uniform criteria and requirements at a national level. The main objective is to protect the freedom of therapeutic choice of citizens and that of treatment by doctors and dentists, both based on a consensual and informed relationship, and to allow citizens to access the care of professionals who have received a suitable training in the disciplines included in the Agreement. Among the main points set out in the explanatory note is the establishment of lists of experts in complementary medicine at the provincial medical associations who can be consulted by citizens and which concern acupuncture, phytotherapy and homeopathy (the latter divided into three sub-lists: homeopathy, homotoxicology and anthroposophic medicine).

It is possible to enrol doctors and dentists who have attended three-year courses of a duration of at least 400 hours of theoretical training provided by accredited public and private educational institutions. To these we must then add 100 hours of clinical practice, of which at least 50% of practical training supervised by a doctor experienced in the specific discipline, and at least 100 hours of individual study and guided training. It is also expected that the courses will be over three years only if the number of hours exceeds the minimum threshold of the training hours provided.

As for the training conducted at a university level, two-year University Masters can be accredited, provided they obviously meet the training criteria highlighted in the agreement itself. The accreditation of the courses will be issued by the region in which the educational institution has its legal office and will have a national value. The recent recognition of the exemption from the CME training obligation has been of a certain importance: on 17th January 2017, in fact, the National Commission for Continuing Education announced that the recognition of exemption from the CME training obligation was approved for surgeons, dentists, veterinary surgeons and pharmacists who attend courses in non-conventional medicine, provided for by the State-Regions Agreement of 5th November 2009.

The National Agency for Regional Health Services (AGENAS) explained that "the accredited training courses under this agreement between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano, concerning the criteria and methods for quality certification of training and practice of acupuncture, phytotherapy and homeopathy, meet the requirements necessary to integrate the types of exemption referred to in paragraph 1 of the decree of the National Commission for Continuing Education of 17th July 2013, on the subject of exonerations, exemptions, individual tutoring, training abroad, self-learning». Therefore it was decided to recognize this exemption linked to CM training in the amount of 4 credits per month of attendance to health professionals taking part in training courses.

From the specific point of view of training in homeopathy, schools in Italy are distinguished by their educational orientation, in three currents of thought.

Unicist Homeopathy - In the search for the most similar homeopathic medicine it is essential to evaluate the whole of the psychological and physical symptoms of each individual, selected on the basis of their most characteristic and peculiar modalities, for the purpose of prescribing the constitutional or simillimum remedy for the treatment of the patient as a whole. The remedy is usually given in a single repeatable dose.

Pluralist or Clinical Homeopathy - To the medicine most similar to the patient, selected with the above criteria, it can be added in the therapy one or more medicines aimed at treating the acute specific symptoms of the disease in progress. Medicines are administered in the various pharmaceutical formulations available; the frequency of administration and the type of formulation used depend on the individual clinical case. This current of thought strives to integrate as much as possible the method of approach to the patient used in homeopathic medicine with that of academic medicine.

Complex Homeopathy - It uses complex formulations consisting of several homeopathic medicines in low dilutions, selected according to synergy and complementary relationships and aimed at both symptomatic treatment of diseases and drainage of the organs involved.

In Europe and in the world the situation is quite heterogeneous above all because the practice of homeopathy in many European countries is still not exclusive to the graduate in medicine; there are therefore schools and training courses at dif-

ferent levels; in Europe it is France that holds the record for the spread of training schools: homeopathy is taught in seven Faculties of Medicine, in 21 of the 24 Faculties of Pharmacy, in two of Dentistry, in two of Veterinary and in three schools for obstetricians with Training Courses divided into 240 hours, structured into three years of attendance.

In Great Britain, the Faculty of Homeopathy in London establishes a training program divided into multiple levels of learning, organizes exams and awards diplomas, accredits and inspects Training Centres held at the Royal London Hospital for Integrated Medicine, at the Glasgow Homeopathic Hospital and at the Oxford Hospital and the courses held and diplomas issued in India and in the Republic of South Africa. In Spain, as in Italy, training schools are essentially private, although for more than 15 years training courses in homeopathy have been provided in collaboration with some prestigious universities (University of Salamanca, Seville, Valladolid, Murcia, etc.). Training programs, public or private, are active in most European countries.

In any case, ECH (European Committee of Homeopathy) is implementing a coordination action to standardize the different schools of homeopathy present in the different countries, starting from the consideration that the prescription of homeopathic therapies must be of medical competence - doctors or veterinarians - (for what concerns the diagnosis/therapy) or the competence of the pharmacist for what concerns the knowledge, dispensation and preparation of the homeopathic medicine.

In the world, instead, India holds the record for the spread of homeopathy schools: 188 university training institutes provide residential courses of a duration of 5 and a half years with mandatory frequency, located throughout the entire sub-continent. The system is coordinated by structures such as the Central Council for Research in Homeopathy and the Central Council of Homeopathy.

In the United States information on homeopathy is provided in many universities, including: Maryland, Columbia, Arizona, San Francisco, New York, California, Pennsylvania and the Harvard Medical School. In 1998, the NHI (National Health Institute) added a section dedicated to Complementary Medicine and the development of scientific research in this sector called NCCAM (National Center for Complementary and Alternative Medicine): in 2014, in the context of a law, called "Consolidated and Further Continuing Appropriations Act, 2015" signed by President Obama, a provision was included to change the name of NCCAM to NCCIH (National Center for

Complementary and Integrative Health). It should be noted that most of the courses have developed in recent years. The laws that regulate the practice of homeopathy in the United States vary from state to state and start from the assumption that individuals who are authorized to practice medicine or another health care profession can legally practice homeopathy. In some states, even non-medical professionals or other health professions can practice homeopathy. Arizona, Connecticut and Nevada are the only states where the diploma of homeopathy is reserved exclusively for medical doctors (holders of the MD degree) and doctors of osteopathic medicine (holders of the DO degree).

A diploma of homeopathic assistant is also issued in Arizona and Nevada, authorized to perform medical services under the supervision of a homeopathic doctor. Some states explicitly include homeopathy as part of the practice of chiropractic, naturopathy and physical therapy and therefore courses for the achievement of these professional diplomas also include homeopathy courses.

Even in Brazil, homeopathy is included in the academic system of some universities, while in other countries the training is delegated to National Schools. In Mexico, training in homeopathy is provided by the National School of Homeopathic Medicine which also depends on the Mexican National Polytechnic Institute. Post-graduate training can be attended at the universities of La Antiquera and Oaxaco.

CONCLUSIONS

The profession of the doctor necessarily requires an academic knowledge. This cultural baggage is essential in the practice of our profession, however we must not neglect the possibility of reflecting on our medical knowledge and striving to increase our treatment capacity. The adoption of homeopathic medicine has allowed us to have a different view of the doctor-patient relationship, of the sense of illness and of healing.

This is in no way in contrast with the practice of the profession in which we have qualified. We believe it is desirable for other graduates like us to be able to use other healing tools that are part of the history and human evolution. We like to think of a medicine free from prejudices that integrates the different therapeutic approaches in the primary interest of patients and that, in respect of its own unity, can rightly be called Medicine.

Moreover, while preserving their own identities and traditions, the opportunities to integrate the thought of complementary medicines into the medical culture of our time are progressively increasing in every part of the world. In addition to the many European experiences, the effort being made in the USA by the Universities and the NHI seems exceptional. The WHO itself works to include complementary and traditional medicines into the health services of the various countries of the world (73).

The possibility of integration requires a sufficient attitude of openness but also an indispensable objectivity. Essentially, integration requires a critical reassessment of the knowledge currently available in modern Western medicine. Doctors and researchers need to be open to considering different interpretations of the concept of health and healing processes compared to the one proposed. During the discussion we have deliberately dedicated a large space to the phenomenon of hormesis because it is our opinion that the studies that are being carried out on the subject could broaden the horizons of future pharmacology.

We are convinced that every doctor who wants to consider the possibility of taking advantage of other interpretation possibilities on the patient and other therapeutic approaches, can be endowed with additional therapeutic tools, without

diminishing their academic knowledge of medicine. The possibility of accepting other paradigms, far from being a sort of threat to the dominant medical thought, could turn out to be rather a further exceptional opportunity. A bias-free medicine can integrate the different therapeutic approaches in the primary interest of patients.

We are aware that, in writing this booklet, we have just provided for an outline. We apologize for this with readers to whom we have offered anything more than an introduction to the knowledge of the subject.

PROFILE OF USERS OF HOMEOPATHIC MEDICINE IN ITALY

The data provided by the World Health Organization (73) state that homeopathy is the second system of medicine in the world, with a growth rate of around 25% every year. Nearly 600 million people in more than 80 countries around the world use homeopathy.

In Europe more than 100 million and in Italy, according to the EMG Acqua 2016 survey (74), 4.5% of the population (around 2 million and 700 thousand citizens) regularly relies on homeopathic care on a daily or weekly basis.

More than 20% of Italians use homeopathic medicines at least once a year. Over 80 percent of interviewees say they know homeopathy.

In 2005, according to ISTAT, (75) the population that had used homeopathy, at least once in the three years preceding the survey, was around 13.6% (more than 7 million 900 thousand people). In 2009, Omeoimprese (the Italian association that represents 90% of the manufacturers and distributors of homeopathic medicines) found that it was about nine million, that is 15% of the population, that used it at least once a year (76).

In 2013, the National Observatory on Women's Health (ONDA) (77) interviewing a sample of 1000 women aged between 25 and 54, found that over 70% of them stated that they had a positive experience with homeopathy. In the following period 2012-2015 Omeoimprese (78) pointed out that the adult Italian population that had used a homeopathic medicine at least once in the previous year had grown, with an increase from 16.2% (in 2012) to 16.5% (of 2015). The use in relation to the geographical area sees the intake of homeopathic drugs by 11.4% of the population of northern Italy compared to 6.8% in the central regions and 2% in the southern regions.

ISTAT, with a study called "Protection of health and access to care" of July 2014 (79), stated that in Italy two million and 452 thousand people regularly use homeopathic medicines, equal to about 4.1% of the population, thus placing the Italians in third place in Europe, after the citizens of France and Germany.

The same statistical data show that about 20 thousand Italian doctors prescribe homeopathic medicines at least once a year. There were 12 thousand in 2006 (Eurispes) (80). The Eurispes 2017 Report on homeopathy (80) is more up-to-date, taking a clear picture of the attitude of Italians towards Complementary Medicine. The report shows that over one in five Italians (21.2% of the population) uses complementary and alternative medicine (with a + 6.7% compared to 2012) and homeopathy is the most widespread integrated treatment.

When it is decided not to rely only on traditional medicine, we first of all aim at homeopathy (76.1%), followed by phytotherapy (with 58.7%) and osteopathy (44.8%), from acupuncture (29.6%) and, finally, from chiropractic (20.4%). To sum up, the population that uses complementary medicines is increasing compared to past surveys.

To a questionnaire submitted in February 2016 (81), carried out by four paediatricians of the CAM group of the FIMP (Italian Federation of Paediatric Doctors) 1,252 paediatricians replied: 98.6% (1237) of them has an agreement with the National Health Service and 60 % has between 600 and 1000 patients belonging to the paediatric age group (0-14 years). Among the 1,252 paediatricians who responded, 29.4% use homeopathic medicines while 70.6% do not use them. The use of homeopathic medicines especially in paediatrics is growing more and more. Almost three out of ten Italian parents use them for their children, particularly from the age of six and above all for respiratory infections. Women choose homeopathy in particular (data from the National Observatory on Women's Health, October 2013) (82), in the age group between 25 and 54, graduates, belonging to the middle/upper class and resident in Italy in the north-eastern and central regions. The exclusively homeopathic therapeutic choice is made by 17% of homeopathy users, while 73.5% associate it with conventional drugs.

73% of those who use it regularly state that they have been very satisfied with the benefits received.

About a quarter of the patients are children younger than or of 14 years of age, who resort to homeopathic treatment especially to treat acute relapsing diseases of the upper respiratory tract. Among adults, over 70% of users turning to homeopathy are patients suffering from multiple chronic diseases, with an important multi-drug therapeutic history, marked by frequent clinical relapses or by illnesses that do not respond to specific conventional pharmacological treatments. According to the data of the international scientific literature, the clinical situations most frequently treated with homeopathy concern:

- respiratory or dermatological allergies of various degrees;
- functional and/or organic disorders of the gastrointestinal system;
- obstetric-gynecological diseases;
- ear nose and throat diseases;
- dermatological diseases;
- inflammatory syndromes (including rheumatological ones);
- respiratory diseases;
- circulatory disorders;
- headaches;
- disorders of traumatic origin.

In Italy, homeopathic medicines are purchased directly by the citizen, who thus takes care of their health without burdening the National Health Service.

Complementary medicines in general and homeopathy in particular therefore reduce health expenditure and prolong life. This is supported by a study published in 2012 in the *European Journal of Health Economics* and conducted by two Dutch researchers, Peter Kooreman and Erik W. Baars of the University of Tilburg (69). The researchers analyzed the insurance data of about 150 thousand people over a period of time ranging from 2006 to 2009. The analysis showed that the patients of doctors who have also completed training in complementary medicine have a lower mortality rate, up to 30%, and a similar reduction in spending on healthcare, with percentages that change in relation to the age group and the type of complementary medicine used. Physicians trained in integrated medicines would tend to advise patients about lifestyles based on prevention and health promotion.

HOMEOPATHY IN THE NATIONAL HEALTH SERVICE

In June 1999, a decree was approved in Italy which included supplementary complementary medicine services within the NHS for the first time. In November 2001 the DPCM defining the LEA (Essential Assistance Levels) excluded these benefits from those that could be reimbursed and paid by the NHS, with the sole exception of acupuncture for indications of analgesia.

In June 2005, the Tuscany region included the services of Homeopathy, Phytotherapy, Acupuncture and Manual Medicine in the Regional Rate Table. This is the first exceptional example in Italy of the inclusion of complementary medicines within the so-called regional LEAs; Tuscany was then followed closely by other Italian regions, so that in table 8 we summarized the 2011 census of the structures that provide clinics of homeopathy within structures of the NHS, maintained in place by autonomous provisions of regional governments; also in 2011 a project was started at the Pitigliano Hospital (ASL SudEst Grosseto - Local Health Authority) of the first regional healthcare facility in Italy where hospitalized patients can take advantage of conventional therapy integrated with the Complementary Medicines recognized by the Tuscany Region (acupuncture, homeopathy), called the Hospital Centre for Integrated Medicine; then within the Regional Centre for Integrated Medicine (formerly the Tuscan Network of Integrated Medicine) which collects and coordinates all the structures that provide complementary medicine services, currently it has been identified as the Regional Reference Centre for Integrated Medicine in the hospital field. The scientific responsibility of the Centre is entrusted to Dr. Simonetta Bernardini, current chairperson of SIOMI.

So, to sum up we can say that compared to 2006, in the Italian regions there is a total of nine regional clinics and 55 less local clinics, except in the Region of Tuscany, where there are 46 clinics more than in 2006, all included in the already appointed Regional Centre for Integrated Medicine. The services are distributed throughout the entire regional territory and in almost all healthcare and hospital companies.

The updated census of these structures can be consulted on the site of the

region, as it is constantly evolving. The services provided are mainly acupuncture (29 clinics) homeopathy (14 clinics), manual medicine (10 clinics) and phytotherapy (4 clinics). Services are also provided for other natural therapies (83).

TABLE 8 - **Complementary medicine in the structures of the Italian NHS**

REGION	CENSUS 2006	CENSUS 2011
■ Valle d'Aosta	3 clinics	1 clinic
■ Piedmont	22 clinics	12 clinics
■ Lombardy	17 clinics	6 clinics
■ Trentino Alto Adige	0 clinics	1 clinic
■ Friuli Venezia Giulia	1 clinic	0 clinics
■ Veneto	4 clinics	1 clinic
■ Liguria	3 clinics	1 clinic
■ Tuscany	66 clinics	75 clinics
■ Emilia Romagna	10 clinics	2 clinics
■ Lazio	6 clinics	3 clinics
■ Umbria	2 clinics	1 clinic
■ Abruzzo	1 clinic	1 clinic
■ Campania	13 clinics	3 clinics
■ Calabria	1 clinic	0 clinics
■ Puglia	1 clinic	1 clinic
■ Sicily	4 clinics	0 clinics
	154 clinics	145 clinics

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