### **EDITORIAL FOR FEBRUARY 2018**

## Clinical Research in Homoeopathy

Clinical research is at the heart of the process for evaluating homeopathy, just as clinical observation is at the heart of medicine. Even more than theory, it is the "clinical" aspect above all which qualifies medical practice.

In homeopathy, the aim of clinical research is to demonstrate the efficacy of the medicines and the prescribing method. While doing so, research also highlights the effectiveness of infinitesimal dilutions, although it is not able to elucidate the mechanisms of action involved. It must be remembered that homeopathy is a customized therapeutic method. In practice, this means that patients with the same disease will not necessarily be given the same homeopathic prescription. For this reason, it is difficult, perhaps even impossible, to carry out double-blind clinical trials. Therefore, when they do exist, they always require a compromise between methodological stringency and the "normal "practice of homeopathic prescribing.

For over fifty years there has been much clinical experimentation carried out in homeopathy (double-blind versus comparison product or placebo) on initiative by different specialized pharmaceutical laboratories or by studies instigated by official commissions. From year to year, methodology has improved due to the influence of the research committees of CCRH and various editorial boards of various international journals where these studies were submitted for publication. After years of hard work and struggle the research committees of CCRH and ECH and the experimenting scientists esp. the great dr. khudabaksh from Kolkata have made it possible for these studies to reach a very high level of quality and to accede to veritable international circulation. In this work we have only retained trials which were approved by the reading committees of the most prominent

scientific periodicals and which had the most promising results. Among these publications, there are two approaches:

° Meta-analyses which assess an entire series of clinical trials and provide conclusions that are both qualitative and quantitative: relevancy of the subject, quality of the experimentation, reliability of the results, statistical overview of the entire body of experimentation undertaken, etc.

Clinical trials, mainly studies published in top periodicals that either prove the efficacy of the homeopathic method in a given disease (with several homeopathic medicines prescribed), or else the efficacy of one homeopathic medicine.

### The homeopathic Materia medica is the combined result of several elements:

The understanding of the objective and subjective toxic effects of a product when high doses of it are absorbed by an individual (intoxication).

The analysis of the physical and mental effects of a product when sub-toxic doses of it are administered to healthy and sensitive volunteers, for a given period of time and according to a very precise protocol (pathogenetic experimentation).

The observation of clinical symptoms which completely subside when a product is medicinally administered in homeopathic doses to ill patients.

# There are three very specific types of difficulties involved in evaluating homeopathic medicines through clinical trials:

For a given diagnosis, there may be different medicines for patients having different types of reaction to this disease

- In divergent diagnoses, the same medicine might be prescribed, especially if it is pathogenetically defined by a vast series of symptoms.

- Last of all, for a given disease in a given patient, a practitioner might change a prescription over time if the medicine indicated at one point in time is not the same as that previously indicated: either due to spontaneous progression or to modifications in a patient's condition brought about by the effect of the medicines initially prescribed.

### Taking individuals into account

In addition to these particular features, homeopathy also involves a holistic view of individuals, which has resulted in the concept of individual "terrain" or constitutional predisposition. The (Hippocratic) habit of homeopathic physicians in observing every patient as a whole, within a specific environment, has allowed them to obtain two different and complementary findings:

On the one hand, certain individuals at a given time and under specific circumstances or constraints have a greater tendency to:

- not only to develop more symptoms,
- but also, to become more sensitized, and therefore better respond to the effect of the homeopathic medication. Scientific observation has shown that these subjects had certain characteristics in common: pathological tendency, character traits and morphological criteria. Whereas the old and classical idea of "constitution" implied a Form of causality between morphology, character and disease tendencies, the modern notion of sensitive type is limited to establishing a link between these symptoms. It makes it possible to identify subjects who are "good responders", thus helping to better identify when to prescribe a medicine and to fine-tune its dosage.

On the other hand, the Family and personal back-ground, the past history of a subject's diseases with their alternation or succession, their continuous or sporadic progression, their circumstances of occurring or healing, all help define a particular chronic constitution or chronic reactive mode for each patient. Here again, whereas the classical and prior notion of diathesis postulated a causality (toxicological, toxin-ological) for this constitutional predisposition, the modern concept of chronic reactive mode simply notes a correlation between these groups of progressing symptoms and the therapeutic claims of certain homeopathic medicines. These medicines effectively impact these constitutions

or chronic reactive modes and the progression of the diseases and treatments.

These two concepts — reactive predisposition at a given moment (sensitive typology) and predisposition over time (chronic reactive mode) — although they differ in theory, are still closely linked in practice and difficult to dissociate. Moreover, if their origins are more to be found in what is innate rather than acquired, it is illusory to attribute a single and exclusive genetic origin because it is true that they are only semiological observations which allow justified and effective therapeutic prescribing. This is their sole object.

Another very important point to make is that this concept of individual constitutional predisposition (or reactivity) only makes sense in pathological circumstances. Indeed, when subjects are submitted to the same strong impact (physical injury or chemical poisoning), it is illusory to believe that their personal reactivity plays a role and that the same lesion or functional effects of those very causes can be identified in identical fashion in every human being. On the other hand, when the impact is lesser, not toxic (change of weather, extreme damp weather or thunder storm), the varied reactions can essentially be explained by their individual reactions. Between these two extremes, all intermediate situations are possible.

It is therefore inexact to say that homeopathy treats patients and not diseases. In practice it either treats diseases or lesions independent of personal reactivity, or treats diseases when personal reactivity dominates, or and this is probably the most frequent case it treats patients and their diseases when lesion or functional symptoms are linked to the cause and the patients' reactive symptoms are combined with them.

The description of these three possibilities shows parallels with the three abovementioned sources of the materia medica: toxicology, sub-toxic dose experimentation, and clinical experimentation. The same sense of semiological observation, the same clinical precision in recording symptoms of the diseases, of the patients and their environments, all of these things which served in drafting the materia medica are necessary for drafting each clinical case. They should be taken into consideration when perfecting every clinical trial protocol.

It is apparent then that homeopathy has a certain number of original features when compared to classical medicine. But these original points, perhaps even called differences, never exist in nosological diagnosis. This is the same diagnosis for all physicians, whether they are homeopathic doctors or not. The last point is essential because it represents the boundary between what is originality practiced in authentic medicine, and other supposedly therapeutic methods which reject the imperious need for precise nosological diagnosis and are merely methods for choosing a remedy by consulting materia medicas and homeopathic repertories, as one might consult a magician.

It is easy to see why followers of this type of view find it useless to carry out controlled clinical trials under scientific method. It is also easy to see why these followers receive backing by detractors of homeopathy, especially if the latter have been recruited in highly-scientific circles.

### **Stringency and ethics**

The cumulated requirements of good clinical trial practices, on the one hand, and of homeopathy, on the other, have resulted in a particularly severe exclusion criterion which make it difficult to recruit patients for these trials.

In homeopathy, clinical trials are also confronted with another requirement that is perfectly logical from an ethical point of view, but leads to an absurd contradiction, from a rational point of view. Impartial reviewers request therapeutic proof according to highly-codified methodologies: the same individuals. Is object to the use of homeopathy, even experimentally, in treating diseases for which there is already an established and active therapeutic solution. This is especially true and is also normal when these diseases can lead to

damaging complications for patients.

For this reason, comparative homeopathic trials have been refused esp. in Europe and USA (homeopathic treatment versus placebo in children suffering from recurring tonsillitis), because such trials would have deprived the patients from antibiotic therapy that is reputed to be not only active but also essential for preventing streptococcic complications: mainly acute rheumatic fever.