Homeopathy Swindle

Do you think it is right to legally prohibit regulatory agencies to require proof of safety and efficacy for products that have legal status and are marketed as drugs? Would you approve use of public funds in healthcare to be spent on the practices equal to shaman treatment or voodoo? Is this possible anywhere in the world? Yes, you are right if thinking this is happening in the European Union. Principles of homeopathy does not have any justification in science and have been proved to be ineffective for many times. It is unsurprising as concepts of homeopathy are derived from mysticism and sympathetic magic.

One would have a luck in 1849 cholera epidemic troubled London to enter the London Homeopathic Hospital. The newly founded homeopathic institutions were immediately credited with highest documented survival rates. But that time was also end of era of mainstream medicine using bloodletting, purging or theriac as sole treatment measures. Homeopathy reached its heights between 1870 and 1890 but subsequently declined fast. 5 of former 22 homeopathic colleges existed in 1919 United States. Today about two percent of population seek homeopathic preparations in the US or the UK. However, the figure is higher in less developed countries.

Philosophical sources of homeopathy can be traced in vitalism which in principle distinct living organism from physiochemical forces and attribute them a vital principle. The philosophy had been still quite prevalent in early 18th century in time of born of homeopathy although its sources in mysticism and supernatural forces. Homeopathy regards diseases to be caused by disturbances in a hypothetical vital force or life force in humans and that these disturbances manifest themselves as unique symptoms. Core homeopathy principles has been formulated as "like cures like" (*similia similibus curentur* in Latin), principle of minimal dose (expressed usually in centimisal or “C scale”) and the single remedy principle.

Guidance on which substances should allegedly be used in accordance with similia similibus curentur principle to treat a particular condition were compiled by Hahnemann and his early followers into books called materia medica. There were wide variations in the amounts of substances administered, the timing of the administrations, the way in which data were recorded, and the length of the studies - and there were no controls. Thus it is impossible to know whether the reported symptoms were actually related to administration of the test substances. Many of listed symptoms are suspicious such as Natrium carbonicum includes "hurries out of bed in the morning", Natrium arsenicum "sickening sensation in left testicle" or "stupidity" for Magnesia sulphurica. Anyway, there is no other then sympathetic magic concept justification. Some illustration of application of the principle may be dubious circumstances of “discovery” of Oscillococcinum which is produced from extract of duck liver and heart and claim to have both preventive and treatment effects in flu.

High dilutions are made by “potentization” where the substance is diluted into alcohol or water and then vigorously shaken by ten hard strikes against an elastic body in a process called "succussion". The vital energy of the diluted substance is assumed to be activated and released by vigorous shaking of the substance. The bottom line is the more diluted the stronger it is! Common sense is enough to assess workability of the idea. Chance that a single molecule of the original substance remain in 30C solution is one to 10^{36}. For more perspective, 1 ml of a solution which has gone through a 30C dilution would

have been diluted into a volume of equal to that of a cube of about 106 light years per side. And of course as the dilutant comes in contact with thousands of different substances thus it can be considered its high dilution. Unsurprisingly, scientific analysis confirm that high dilutions does not have any physiological effects under laboratory conditions (Ovelgonne et al., 1992; Hirst et al., 1993). For correctness it should be noted that not all homeopathic products are made as high dilutions. In some (minor) cases dilutions such as 2C to 6C applies in which the active substance is detectable.

Homeopathy acknowledge that it has not explanations for supposed mechanism of action of its preparations. The proposed explanation is that dilutant has a "memory" to store the vital power purportedly by forming non-covalent structures and therefore remain active even if substance is not present. However, it has been proved that non-covalent structures in liquid water at room temperature are only stable for a few picoseconds (Teixara, 2006).

On base of the presented facts clear conclusions could be made on clinical value of homeopathic preparations. Their uselessness could not have been disputed but this has not been the case. Clinical trials rather brought new disputes and had not been able to provide conclusive evidence for a long time. And not just that – homeopathic preparations are today marketed as drugs with therapeutical claims in indications including asthma, osteoporosis, tuberculosis, cancer, anthrax infection and many others marketable conditions.

Some of homeopathy clinical trials presented claims on superiority of homeopathy over placebo. These include Weiser et al. (1998), Weiser et al. (1999), Oberbaum et al. (2002) and others which suggested better results of homeopathic preparations over placebo within significance area. Linde et al. (1997) concluded in complex meta-analysis published in Lancet that "The results of our meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo". This claim became immediately presented by homeopathy proponents as compelling evidence of effectiveness. In fact the author highlighted in the article that "we cannot completely rule out bias as an explanation for these results" and concluded "Our study has no major implications for clinical practice because we found little evidence of effectiveness of any single homeopathic approach on any single homeopathic condition".

Linde (1997) conclusions brought attention to methodology and evidence for bias. It is understood that conduct of a clinical trial producing reliable and reproducible results is sophisticated task. Just to have a quick overview on technical and legal requirements of clinical trials that are conducted in order to prove effectiveness in new drug application you may check International Conference on Harmonization Efficacy Guidelines or Eudralex - Volume 10, Clinical trials of Notice to Applicants working group (that I was member some time ago) of the European Commission. Linde (1998) eventually adjusted his conclusions and admitted that there were substantial methodological issues in the considered trials and there are no grounds to assume efficacy of homeopathic preparations. Better results of homeopathy were in trials of lower methodological quality. On the other hand homeopathy trials in general failed to bring significant effects in double blind placebo studies. Methodology shortcomings has been confirmed by up to date the two most complex meta analyses: Shang et al. (2005) published in Lancet and by Millazo et al. (2006) of European Journal of Cancer. Recent evidence seems to be strongest ever presented to place homeopathy in area of pseudoscience.

I am not at all supporter of ban on homeopathic preparations. Anyway, there are many other products with magical treatment claims on the market. However, there are issues that make homeopathy distinct and special from other mysticism based quackery. That is the drug legal status and in some cases public funding.

Legislation in both the US and EU provide specific status for homeopathic preparations. The crucial distinction is that proof of efficacy is not required. The European legislation states that homeopathic "medicinal products" supposedly can not be subjected to established scientific evaluation methods and

therefore special approach of simplified registration procedure shall apply as written down in Initial provision (21) of EU Directive 2001/83/EC on the Community code relating to medicinal products for human use :

Having regard to the particular characteristics of these homeopathic medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those homeopathic products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient

Simplified registration means notably as stated in Article 14.3 that

The proof of therapeutic efficacy shall not be required for homeopathic medicinal products

The fact that the governments consider homeopathic products effective is hurting credibility of the regulatory agencies. Furthermore under the same directive homeopathic preparations are considered safe on base of their high dilutions (Article 14.1) and safety profile of excipients is not considered. However, it is not true that there have not been safety concerns on homeopathy. One of points is that preparations for children in some cases contain higher concentrations of alcohol then it is permitted in other approved drug forms. Worth of remark is also curious case of Zicam lawsuit which resulted in 340 settled cases worth of $ 12 M. In the case Zicam Cold Remedy manufacturer (Matrixx) was suit of alleged caused harm by their homeopathic nasal spray which allegedly caused permanent loss of smell in some users. As the case was settled there have not been court verdict. The manufacturer claimed that harm was because of improper use. On the other hand lawsuits allege that Zicam damaged fragile smell tissue as a result of the drug's pump bottles, which drive the thick gel into the top of the nose with great force. Also it is proven that zinc can damage smell in sufficient concentrations and known that 2X (1:100) dilution was used in the product. Wherever the truth lyes this points out to another important issue that combination of too broadly defined standards of homeopathy and absence of toxicological testing can bring dangerous products. Beside this, fact that homeopathy practitioners often discourage patients from use of allopatic medication and prohibit them from receiving proper treatment is obvious. As disturbing may be viewed homeopathy treatment claims of serious conditions such as cancer, HIV, stroke. Some accuse homeopathy producers of illegal marketing often backed by FDA warning letters.

Despite all the evidence some European countries cover some homeopathic treatment by the national insurance coverage. These include UK, Denmark, Luxembourg. Since 2004 and 2005 respectively homeopathic preparations are not any longer covered in Germany and Switzerland. Public funding of homeopathy is also under increasing pressure in the UK.

In my opinion homeopathic preparations do not deserve any special status and the European legislation should be in agreement with current scientific knowledge. The preparations should be allowed to be marketed as nutritional supplements only unless clinical trials evidence of efficacy is not provided (what had never happen until now). Also, there is not any rational justification for absence of toxicological data which are required in nutritional supplements as well. Use of public funds for the quackery is shameful waste of resources.