

# ECHAMP NEWS

Brussels

October 2005



**European Health Forum Gastein 5-8 October 2005**  
**ECHAMP Workshop - 5 October (18h30-20h00)**  
**Complementary medicine – an efficient and safe contribution to patient satisfaction?**

<http://www.ehfg.org/en/congress/W4.php>

## LANCET LASHES OUT AT HOMEOPATHY



On 27<sup>th</sup> August the Lancet published the study "Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy" by Ajing Shang. An editorial predicted "The end of homeopathy".

Editor McCarthy wrote about the bias in the leaked preliminary report on the science base of homeopathy by the WHO, admitting, however, that "homeopathy is extremely popular and its use is on the upswing worldwide".

Following this issue, there have been strong reactions from all over the academic world demonstrating areas where the article does not meet the minimum conventional criteria for publication in biomedicine.

A letter to the editor and Echamp's position can be found on the website [www.echamp.org](http://www.echamp.org). More opinions from the scientific world can be found on [www.homeopathycourses.com/lancet.html](http://www.homeopathycourses.com/lancet.html)

Hopefully the result of the present polemic will be that new ways and funds will be found to research complementary medicine and homeotherapy in particular. It cannot be true that the millions of satisfied users over 200 years are wrong. Nor can it be right that politically the prerogative of health-care is given to allopathy only.

## ACADEMIC WORLD RESPONDS TO LANCET PUBLICATION

*Dr. P Fisher, Clinical Director of the Royal London Homoeopathic Hospital:* "There is a strong suspicion that the results are being spun." The conclusion that "the clinical effects of homeopathy are placebo effects" is based on only 8 unreferenced clinical trials - and no further information given. Requests to Prof. Egger, who wrote the first draft of the study, to disclose the titles of the studies used, hit a wall of silence.

Fisher underlines that all three current meta-analyses on homeopathy (including the one that was left out by Shang) show positive results for homeopathy. He concludes that the paper is not transparent and fails to meet the norms of a good scientific report:

"a reader should be able to reproduce it on the basis of the report".

Others are concerned about the literature review in which apparently eligible high quality studies were left out and others inappropriately included.

*Dr. Robert Mathie (website of Faculty of Homeopathy, UK):* Lancet article is fundamentally flawed, the paper has not demonstrated the homeopathy's lack of benefit. Regrettably, in publishing and commenting on this paper, the journal has displayed some of these unwelcome attributes of selective analysis and biased reporting. An investment in clinical research in homeopathy needs to be enhanced, not withheld.



**George Lewith (University of Southampton, UK):** The six studies of conventional interventions are highly selected. The substances have gone through four clinical pharmacological stages of drug testing. The vast majority of newly developed do not make it to that last stage of Phase IV trials. Therefore the trials chosen by Shang had already been proven to be efficacious. Homeopathic trials start from a far less systematic and rigorous evidence base. There have, after all, been very few RCT's in homeopathy which is why there is an absence of evidence. *We are only just beginning to understand how to research homeopathy and CAM in general. This seems to be an argument for more research investment, not less.*

**Prof. Iris Bell (University of Arizona, USA):** The politics of the homeopathy debate right now are so blatant, as the position against homeopathy ignores the observational data and the animal data and the preclinical data in the literature as though they did not exist, let alone that they show significant effects and unique properties of remedies.

**Sally Penrose (Chief Executive of the Faculty of Homeopathy, UK):** "Patient outcomes studies at the NHS homeopathic hospitals show that on average 70% of patients report positive health changes after homeopathic treatments - these patients who have usually exhausted all the conventional options first and are coping with intolerable suffering."

**Mikel Aickin (Biostatistician University Arizona, USA):** After distinguishing five areas in which the Lancet does not meet the minimum conventional criteria for publication in medicine, he observes "a continued degradation of methods in biomedical research, supported by "leading" journals" and ponders that it might be time to think about the "End of Biomedical Journals" as we know them. The duty of publishing all funded research and much of the unfunded research could be laid in hands of a body like the National Institutes of Health (NIH), through the National Library of Medicine. That would safeguard an operation under rational regulations.

(FB)

#### SWISS STUDY DEMONSTRATES THE EFFECT OF HOMEOPATHY IN HYPERACTIVE CHILDREN

(FB) A study performed by KIKOM (Kollegialen Instanz für Komplementärmedizin der Universität Bern) and the "Medizinischen Universitätsklinik Bern" has demonstrated the efficacy of homeopathic medicinal products in children with an Attention Deficit Syndrome (ADS). The study was published in the "European Journal of Paediatrics". The findings are in opposition of the recently

published meta-analysis by the "Institut für Sozial- und Präventivmedizin" of the Bern University labelling homeopathy to be just a placebo effect. An interdisciplinary research team of that University directed by Dr. med Heiner Frei came to the conclusion that ADS symptoms like hyper activity, shyness or anxiety decreased by 37 till 63 percent. The learning behaviour improved and the duration of the positive effect was for a longer period of time.



From 2001 to 2005 the researchers followed the effects of homeopathic treatment in children with ADS. After a neuropsychological and neurological check the children were individually treated by a homeopathic physician. The data were collected according to the double blind cross over method. Neither the patient nor the doctor knew who received the placebo or the real medicine. During the treatment the children were regularly examined by a neuro-psychologist.

This positive result puts the homeopathic treatment for ADS patients on an equal level with regular medicine, the latter treating the children with medicinal substances which had effects on the psyche, often with side effects. According to Dr. Frei the homeopathic treatment has a favourable cost effect.

(Source: Deutscher Zentralverein homöopathischer )

#### IN MEMORIAM DR. MARIANNE HEGER

(FB) For many of us the death of Dr. Marianne Heger came unexpected. Those with whom she used to work with suspected an illness, however, no clear signals were received about the severity. That made the shock created by her decease even greater.

ECHAMP will remember Marianne as one of the few of the first moment who saw the need for a European coalition of manufacturers of homeopathic medicinal products. She devoted a part of her abundant energy in the conversion of EACH into ECHAMP.



With her vision she had a roadmap clear in her mind and sometimes wondered why others could not follow her quick pace.

After becoming a Doctor of medicine in 1986 she followed a postgraduate education in naturopathy, homeopathy and acupuncture. She gained practical experience in internal medicine and had a private practice until 1992. She took positions as a Medical Advisor at Bristol-Meyers Squibb and in international marketing at Knoll AG before becoming Director of Science and Research at the DHU in Karlsruhe.

Marianne Heger was the driving force behind many research projects and a great propagator of outcomes and observational studies. That resulted in IIPCOS-1 an international prospective outcome study executed in six study centers in Germany, Austria, Switzerland and the USA. Being a member of among others, the German Association of Homeopathic Doctors, the Association of Naturopathic Doctors, the American Institute of Health (AIH), the International Homoeopathic Medical League (LMHI), the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), she could count on a vast network of prominent homeopaths and innovative researchers. Her name is connected with an impressive list of publications and projects.

Her creative powers, sense of responsibility and extraordinary expertise made her a special person. The overall objective was always to support and expand the science base of homeopathy - an aim she pursued with an incredible engagement.

Marianne Heger was an ECHAMP Board Member from the founding of the organization in 1999 until 2003 during which she was vice-president, the working group Public Relations and of course the working group Research. She was 49 years old. The homeopathic community will miss her.

## ECHAMP Agenda

SEP 29	SG CTD	Cologne
OCT 5	EHFG - ECHAMP Workshop	Gastein (Austria)
OCT 5-8	European Health Forum	Gastein (Austria)
OCT 12	WP CEEC	Karlsruhe
OCT 31	SG Nosodes	Baden-Baden
NOV 24-25	Board Meeting	ECHAMP Brussels

## NEW LICENSING FOR HOMEOPATHIC MEDICINES IN THE UK



(KC) After long anticipation, the MHRA has started public consultation on new proposals for the licensing of homeopathic medicines.

Article 16.2 of the European Medicines Directive (2001/83/EC) allows the UK to introduce 'National Rules' for the licensing of homeopathics in accor-

dance with the principles and characteristics of homeopathy as it is practised in the UK.

The proposals under Article 16.2 allow for the inclusion of therapeutic indications on the packaging of many homeopathic medicines. This is a breakthrough for the homeopathic medicines industry. The fact that therapeutic indications may now be included on the packaging of licensed homeopathic medicines will not only open the practice of homeopathy up to new users but also give it added credibility as a safe and natural complement to orthodox medicine.

It will also allow a broader range of products including lower potency (less dilute) homeopathic medicines.

Under current licensing arrangements homeopathic products either have Product Licences of Right (PLRs) or have been granted homeopathic registrations (HRs) under the Simplified Scheme. PLRs were issued in 1971 to all homeopathic products on the market at the time of the Medicines Act 1968. Homeopathic products covered by PLRs may have indications on pack.

The Simplified Scheme was introduced in 1992 by Directive 92/73/EEC; it does not allow indications. There is no requirement for data to demonstrate efficacy.



Present legislation means that, due to the exclusion of therapeutic indications on any newly licensed homeopathic products, consumers can be confused by both the range of homeopathic products available and their purpose. The new legislation will correct an anomalous situation, whereby two products can sit side by side, one with indications and the other without, depending when they were licensed.

Under the proposals, OTC type indications will be allowed for specified ailments, based on relevant bibliographic sources (materia medica and other) and practitioner experience. The range of indications will be limited to minor, self-limiting conditions such as travel sickness and nausea, minor skin conditions, hay fever, and muscular pain and stiffness. It will exclude serious diseases such as cancer, diabetes, cardiovascular diseases, chronic insomnia or psychiatric conditions.

Packaging, point of sale materials and merchandisers will all be able to contain more information, with a focus on ailments, making it much easier for individuals to self-select OTC homeopathic remedies and for pharmacists with limited experience of homeopathy to recommend OTC homeopathic medicines for acute or first aid conditions.

The new legislation will also allow for the development of new products, with indications, introducing much wider choice for consumers.

Currently unlicensed homeopathic medicines are not allowed on the UK market. With clearer 'rules' regulatory enforcement should also become more effective.

This legislation is aimed at licensed products, such as are available OTC. It doesn't directly affect manufacturers of 'Special' homeopathic medicinal products, so there is no foreseeable impact on practitioner prescribing.

The new scheme is scheduled to be implemented in the UK by 1 January 2006. It is estimated to take between six and twelve months for the new licenses to be issued, which means the first implications will be seen from late 2006/early 2007.

*The consultative paper was published on 21 June (MLX 312: Licensing of homeopathics: proposals for a new National Rules Scheme, for a review of product licences of right and to expand the remit of the advisory board on the registration of homeopathic products (ABRH)). The consultative period closed on 12 September 2005. For further details on the consultative paper visit [www.mhra.gov.uk](http://www.mhra.gov.uk).*

### THE SCIENCE BASE OF HOMEOPATHIC AND ANTHROPOSOPHIC MEDICINE



(FB) A new ECHAMP brochure provides information on homeopathic research. Written by a science journalist, the content is well accessible for readers with little time to spare, like politicians, civil servants and journalists. The wide scope presents a bird's eye view of

homeopathy's and anthroposophic medicine's fundamental research and clinical trials, human and veterinary studies. Copies can be ordered at the ECHAMP Office: ([office@echamp.be](mailto:office@echamp.be))

### INDIA QUESTIONS THE EU ON AYURVEDIC MEDICINES: GLOBALISATION IN CAM?

(NDH) The Indian Industry Minister Kamal Nath has urged the European trade Commissioner Peter Mandelson to deal with the problems Indian exporters of ayurvedic products to Europe face because of the renewed European Medicines Directive.



In a letter to Mandelson Mr. Nath has pointed out that, as a consequence of the provisions regarding traditional herbal medicinal products, most ayurveda products would never find a place in the European Union due to the condition of a minimum 'traditional' and safe use of 15 years within the

EU. «This condition is neither scientific nor based on any risk analysis and has the effect of an insurmountable non-tariff barrier to trade» he adds.



An EU-India summit took place in September but the outcome of this specific item on the Agenda is not known so far. It seems that an EU-India trade action plan will also provides for a joint working group on pharmaceuticals. Its responsibilities will include the marketing of ayurveda medicines in the EU.

Mr. Nath has proposed deferring the implementation of the revision (which should be finalised on October 2005) till the matter of the ayurvedic products is resolved by means of proposals to be made by the joint working group. The pressure of Asia on the EU focussing on barriers and over-regulation increases in many different areas!

**Are you interested in publishing information on homeopathy or anthroposophic medicine?**

**Do you want to highlight an event or activity?**

Please send in regulatory news, research projects, publications, conferences, etc. to

[office@echamp.be](mailto:office@echamp.be)

Deadline for an article is the 20<sup>th</sup> of each month.

For the editing team, Ellen Van Rompaye

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