

ECHAMP NEWS

EUROPEAN COALITION ON HOMEOPATHIC & ANTHROPOSOPHIC MEDICINAL PRODUCTS

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EDITORIAL



Sunny and hot July, wet and cold August, hope for September... the shortest possible description of this summer. I hope that you have enjoyed it and that the start of the 'new term' has been successful.

As far as ECHAMP and the whole CAM community are concerned, we are facing a hot and busy autumn and winter.

On the political agenda we await the final decision on the Seventh Research Framework Programme at the end of November. The official EU Regulatory Affairs agenda includes two meetings of the HMPWG (one in November and a second one in the first semester of 2007). We also look forward to some improved activity regarding Regulatory Affairs for our products during the German EU-Presidency in the first part of 2007. The different pharmaregulatory affairs working parties within ECHAMP are actively dealing with major topics such as CTD (form, content and guidance), Mutual Recognition (MRP and DcP), European Pharmacopoeia, Safe Concentration Levels, Nosodes etc., preparing for an exchange that we hope will take place with European and national competent authorities, the European Commission, the EMEA, the HMPWG and the national authorities in the coming 'working year'.

Our members and other CAM stakeholders have high, and indeed legitimate, expectations regarding clarification on a number of issues by means of proper exchange of views. The 'Availability, Accessibility and Affordability' of homeopathic and anthroposophic medicinal products all over the European Union (i.e. free circulation) as demanded by more than 100 million EU citizens can no longer be neglected.

Nand De Herdt
General Secretary

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RESEARCH

THE 7th RESEARCH FRAMEWORK PROGRAMME

The latest steps on FP 7

(PS) On 24 July 2006 the Council of Ministers reached a political agreement on FP 7. This includes the amendment on Complementary Medicine (CAM). The qualified majority which was needed has been achieved.

However the focus on Complementary Medicine was less than expected. The actual reference to CAM was incorporated into another point, rather than being included as a point on its own as follows:

'Optimising the delivery of health care to European citizens' - Translating clinical research outcome into clinical practice. To create the knowledge base for clinical decision-making and how to translate outcomes of clinical research into clinical practice and especially addressing patient safety and the better use of medicines (including some aspects of pharmacovigilance and scientifically tested complementary and alternative medicines) as well

as the specificities of children, women and elderly population.

What happens next?

The MEPs are expected to start the second reading on 29 November; the European Parliament will consider and vote on the 'counter-proposals' in the Common Position; in this reading an amendment needs an absolute majority of the total number of MEPs (732) which means at least 367 votes in favour. There is furthermore the possibility that a third reading (Conciliation) will be done, but given the tight time pressure this chance is very low. The 6th Framework Programme (FP6) will run until end of 2006. First calls for proposals under the EU's FP7 are expected at the end of 2006. Technical scope, participation rules and administrative procedures are all currently under discussion and negotiation between the Commission, the European Parliament and the EU Member States.

Nevertheless Complementary Medicine has taken a big step onto the European Agenda, at the very least in the heads of the MEPs. With its positioning in the FP7 the door has opened a little for EU funding.

Of course our aim continues to be to open it completely! With this in mind, ECHAMP will focus on awareness raising events for CAM at the European Parliament close to the second reading.

EFFECTIVENESS OF HOMEOPATHY AND ANTHROPOSOPHIC MEDICINE CONFIRMED

Abridged Versions of the HTA Reports of the Swiss PEK (Program Evaluation Complementary Medicine) now available

(MD) In June 2006 a supplement edition of the journal *Research in Complementary Medicine, Forschende Komplementärmedizin*, edited by P. Heusser, Bern, H. Walach, Northampton, and U. Wolf, Bern, published the *Abridged Versions of the HTA Reports of the Swiss PEK (Program Evaluation Complementary Medicine)*, on three of the five therapeutic approaches which were assessed, namely Homeopathy, Anthroposophic Medicine, and Traditional Chinese Medicine (TCM).

The PEK initiative goes back to a decision by the Swiss Health Authority in 1998 to allow five disciplines of Complementary Medicine (CM), namely Anthroposophic Medicine, Homeopathy, Neural Therapy, Traditional Chinese Medicine, and Phytotherapy, to be reimbursed by the state insurance system for five years. At the same time an evaluation program (PEK) was initiated to find out about effectiveness, safety and cost-effectiveness of these complementary therapies. For that scope three research projects of different methodological

approach were used: empirical field studies, meta-analyses of placebo controlled clinical studies, and Health Technology Assessments (HTAs).

The latter considers the effectiveness, appropriateness and cost of technologies. It does this by asking four fundamental questions: Does the technology work, for whom, at what cost, and how does it compare with alternatives.¹ Its value is especially considered in political decision making processes.

Such a large scale compilation of data in the area of Complementary Medicine has never been available before. Compared with the full HTAs which contain an enormous amount of data², the abridged versions allow a more rapid access to data and results. They are complemented by articles on demand and use of CM in Switzerland and on cost aspects.



Some of the review articles are published in English, some with an English summary but the editorial contributions with most interesting explanations and background information unfortunately only come in German. Ursula Wolf from the Berne University Complementary Medicine Institute for instance makes it clear

that the Swiss Government (Bundesrat Couchepin) decided to stop reimbursement for CM in 2005 despite the opposite overall result of the PEK data. She stresses the unique compilation of literature regarding effectiveness, usefulness and cost-effectiveness which has added value to the discussion about CM and produced valuable additional information.

Conclusions in the review articles show positive results in all three therapy areas. For homeopathy effectiveness "can be supported by clinical evidence" and adequate application can be regarded as safe. In anthroposophic medicine "trials ... predominantly describe good outcome" and for TCM therapy "basic clinical effectiveness" is accredited. However, the authors also mention that at the moment there are no reliable data regarding cost-effectiveness.

Another result in all three areas, according to Wolf, is an apparent need for further research development in basic and in clinical research and also in methodology. For instance, aspects of internal and external validity should be taken into account in order to be able to recognise context relations in treatment schemes.

All in all, despite the questionable decision by the Swiss health authority, these extensive and high

quality reports should definitely help to create a positive climate for further investigation and also for funding of research projects in Complementary Medicine by the European Union in its 7th Research Framework Programme and by national and private institutions.

Link to the [Forschende Komplementärmedizin](#) magazine.

¹ UK National Health Service R&D Health Technology Assessment Programme 2003

² Available in German and in English: Kienle GS, Kiene H, Albonico HU. *Anthroposophische Medizin in der klinischen Forschung*. Stuttgart: Schattauer, 2005.

Bornhöft G, Matthiessen PF (eds.). *Homöopathie in der Krankenversorgung. – Wirksamkeit, Nutzen, Sicherheit und Wirtschaftlichkeit*. Frankfurt a.M.: VAS, 2006, in press, in German and in English.

EU MASTER IN SCIENCES OF COMPLEMENTARY HEALTHCARE

(FB) In December 2004 representatives of a network of 35 European universities signed an agreement to develop a master study in the field of CAM (Complementary Alternative Medicine). The initiative is part of the "Leonardo da Vinci - programme" of the European Commission. In April 2005 the first group of 120 students from various disciplines in health care graduated. In March 2006 a new study group has started on a campus site located in Copenhagen (Denmark). In 2008 the next group will start. More info on: www.inter-uni.net

ARTICLE 16 : IMPLEMENTATION GUIDE

(JH) Potentially the most controversial EU legal provision regarding the licensing of homeopathic medicinal products is Article 16 of Directive 2001/83/EC. The Article lays down rules for obtaining marketing authorizations for homeopathic medicinal products which cannot be registered according to the special simplified registration procedure (Article 14(1) of Directive 2001/83/EC). To be more specific, Article 16 applies to those homeopathic medicinal products that contain potencies lower than D4 or C2, display a medical indication, or are applied through other than oral or external routes.

As a point of departure, Article 16(1) declares the general requirements for marketing authorization as defined in Directive 2001/83/EC equally applicable to homeopathic medicinal products which are outside the scope of the special simplified registration procedure. However, the optional Article 16(2) gives Member States the competence to deviate partially from these general requirements with respect to preclinical (pharmacological and toxicological) tests and clinical trials, in order to better suit the special character of these type of medicinal products. According to the Article, if a

Member State chooses to adopt special rules it should inform the European Commission thereof.



Major criticism with regard to Article 16 concerns the optional character of the second paragraph, since it leads to national rules which are counterproductive to the European harmonization effort with regard to

homeopathic medicines legislation as a whole. In its 1997 Report on the application of Directive 92/73/EEC and 92/74/EEC on homeopathic medicinal products for human and veterinary use,¹ the Commission identified 6 Member States which adopted special rules under Article 16(2).² Furthermore considerable differences between these rules were established, adding to the general conclusion that "a certain but not yet satisfying degree of harmonisation had been achieved in 1997".³ Although the abolishment of the optional character in exchange for harmonized special rules has been proposed a number of times, it has not been held politically feasible until now.

The discussion on Article 16 has without doubt lacked clarity on the exact regulatory situation in the EU, as have many other issues with regard to national rules and administrative practices regarding homeopathic and anthroposophic medicinal products. Therefore ECHAMP has set up a research programme to map the exact implementation situation in the respective 25 member States. The programme has revealed that currently 12 Member States have adopted special requirements under Article 16(2) which differ considerably.⁴ This is an increase of 100 percent compared to 1997! On top of that, 9 additional Member States have provided the option to adopt special rules directly in their legislation!⁵ Harmonization of the marketing authorisation requirements for homeopathic and anthroposophic medicinal products is thus more necessary than ever before.

From ECHAMP's findings on the implementation of Article 16 an 'implementation guide' has been prepared, which not only files the national provisions implementing Article 16 of Directive 2001/83/EC, but also contains unofficial translations of these provisions in the English language. The document titled "The implementation status of Article 16 of Directive 2001/83/EC (Interim Report June 2006)" has been published on the ECHAMP website under 'Statements' and thereafter 'Our Documents'. For a direct link you can [click here](#)

¹ Homeopathic Medicinal Products, Commission report on the application of Directives 92/73/EEC and 92/74/EEC regarding Homeopathic Medicinal Products, COM(1997)362 final

² Commission report on Homeopathic Medicinal Products, supra note 1, pp. 6-7.
³ Commission report on Homeopathic Medicinal Products, supra note 1, p. 8.
⁴ ECHAMP, *The implementation status of Article 16 of Directive 2001/83/EC (Interim Report June 2006)*, ECHAMP Office Brussels, 28 June 2006.
⁵ Ibid. note 4.

HOMEOPATHY IN SOME OF EUROPE’S MAJOR MARKETS



(FB) In Germany at the moment homeopathy is the most beloved therapy in complementary medicine. Acupuncture ranks on the second place.

The cost of the therapy are mostly being taken care of by private health insurance companies. 4500 German practitioners have received a post graduate education in homeopathy, however, also in other European countries the dissemination of this specimen of green medicine is growing. In the UK health care is free at the point of delivery, so for those whose doctors are qualified in homeopathy there is no extra charge. There are five homeopathic hospitals in the UK, all run by the National Health Service. In France a special approach in the form of “homéopathie clinique” has been developed over a number of decades. For a long time in France 65% of the cost of medicines were reimbursed. In the beginning of last year this percentage was reduced till 35%. Belgian patients are reimbursed between 25 and 100% depending on the health insurance company.

In contrast with Belgium and France where only doctors may practice homeopathy, in the UK and Germany the treatment of patients can also be done by naturopaths. In Sweden as an extreme, doctors are prohibited to treat patients homeopathically.

Sources:

- ECHAMP Editor sources
- Arte - [Hippokrates Gesundheitsmagazin](http://www.arte.tv) 23.05.2006

FOCUS ON HOMEOPATHY IN THE NETHERLANDS



(FB) 2005 was an eventful year for homeopathy in the Netherlands. Neprofarm’s (the Dutch manufacturers’ association of proprietary medicines) annual report gives a comprehensive

review of all the events concerning homeopathic medicinal products since 2002 and their outcome. In



2005 Neprofarm and the Ministry of Health had a serious dispute about the application of a disclaimer on homeopathic medicinal products with a marketing authorization. The Council of State - highest juridical body in the Netherlands - had ruled that such a disclaimer was not in line with European law.

The minister of health was of the opinion that omitting a disclaimer could only be justified by demonstrating the efficacy according to conventional scientific criteria. The competent authority - the CBG-MEB - reacted promptly by refusing to register homeopathic medicinal products with a therapeutic indication until further notice.

A pragmatic approach by Neprofarm finally resulted in a solution which struck a balance between finding a different way to assess a specific indication and the guarantee that the user will be informed appropriately. The annual report can be downloaded at www.neprofarm.nl (in Dutch only).

ECHAMP Agenda

Sep 13-14	Board Meeting	Karlsruhe
Oct 18	SG Mutual Recognition	Bensheim
Oct 26	WP Public Relations	ECHAMP Brussels
Oct 27	EMEA Workshop Homeopathy	London
Nov 23-24	Board Meeting	ECHAMP Brussels

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