

ECHAMP NEWS

EUROPEAN COALITION ON HOMEOPATHIC & ANTHROPOSOPHIC MEDICINAL PRODUCTS

Brussels

November 2006

EDITORIAL



October has been an important month for homeopathic and anthroposophic medicines in a European context, with a number of interesting meetings, covered in this issue of ECHAMP news. Firstly, there have been intensive discussions in the High Level Group on Pharmaceuticals, the enlarged former G10 Medicines Group; Commissioner Verheugen himself has expressed his concern about the result of the recent revision of EU legislation on pharmaceuticals.

Secondly, ECHAMP was represented at the yearly 'LIGA Congress' in Switzerland, the Liga Medicorum Homeopathica Internationalis (LMHI) and thirdly, we had a special meeting with our German associated member Bundesverband der Pharmazeutischen Industrie (BPI) to discuss the opportunities presented by the Germany Presidency of the EU in the first half of 2007 for Complementary Medicine and its medicinal products (*Besondere Therapierichtungen*).

But most important was the workshop hosted by the European Agency for the Evaluation of Medicinal Products (EMA) on the situation, the legislation and the regulatory environment concerning homeopathic and anthroposophic medicinal products in the European Union. All the key stakeholders - manufacturers, doctors', practitioners', pharmacists' and patients' organisations - took part as reported in this newsletter. EMA will publish an official report in due course.

And last but not least the ECHAMP office is moving in November. Although in the shadow of the large buildings of the European institutions, our new office has plenty of space and light. It will be an ideal place for us to work even more enthusiastically towards our goals for the association. You are most welcome to visit us.

Nand De Herdt
General Secretary

TABLE OF CONTENTS

■ EMEA Homeopathy Workshop	1
■ Pharmaceutical Forum 2006: Speech of Commissioner Verheugen	3
■ 61st Congress of LIGA in Lucerne	3
■ Liga 2007-Puebla, Mexico & Liga 2008-Oostende, Belgium	4
■ ECHAMP & BPI	4
■ Legal update: Lithuania	5
■ ECHAMP moves!	5

HOMEOPATHIC WORKSHOP AT EMA



On 27 October 2006, eleven European associations were invited by the European Agency for the Evaluation of Medicinal Products (EMA) to a Homeopathic Workshop in London. ECHAMP was represented by Dr. Gesine Klein and Nand De Herdt. The following associations also participated in the workshop: Association of the European Self-Medication Industry (AESGI), Comité International des Pharmaciens Homéopathes (CIPH), European Council of Classical Homeopathy (ECCH), European Committee for Homeopathy (ECH), European Council for Doctors for Plurality in Medicines (ECPM), European Federation of Homeopathic Patients' Associations (EFHPA), European Federation of Patients' Associations for Anthroposophical Medicine (EFPAM), International Association of Anthroposophic Pharmacists (IAAP), and International Federation of Anthroposophic Medical Associations (IVAA).

Eighteen national medicines agencies were also represented, with good representation from the EMA itself, participants from the European



Directorate for the Quality of Medicines (EDQM) and the World Health Organisation (WHO) and the chairperson of the Co-ordination Group for Mutual Recognition and Decentralised

Procedures (human) (CMD(h)), Ms. Truus Janse-de Hoog.

The workshop was chaired by Tony Humphreys, the Head of Sector Regulatory Affairs and Organisational Support of EMEA.

The agenda was based on input from key stakeholders and created a clear and comprehensive framework for discussion. This gave the opportunity to bring the most important regulatory issues and problems to the table. The proposed topics for discussion were the regulatory framework, the Homeopathic Medicinal Products Working Group of the Heads of Agencies (medical authorities in the EU) (HMPWG), the European Pharmacopoeia, Common Technical Document (CTD) and dossier requirements.

In his introduction Thomas Lönngren, Executive Director of the EMEA, pointed out that the EMEA had been asked by the European Commission and by a number of MEPs to organise this meeting. The EMEA does not currently deal with homeopathic and anthroposophic remedies nor does it have any responsibility to do so at the moment. Its role at the workshop was to provide a platform for discussion. The EMEA will publish a summary report of the workshop and will also send a longer report to the participants, the European Commission and the MEPs who had asked for an EMEA initiative in this field.

Each participating association had the opportunity to present itself and its points of view. In this part of the workshop the problems of patients and practitioners were strongly stressed, in particular concerning availability and accessibility of treatment and self-medication and availability to be able to treat patients.

The four main agenda items offered the opportunity for constructive and lively discussion about the status quo of European harmonisation and application procedures for homeopathic medicinal products. The topics "Regulatory Framework" and "HMPWG" were introduced by clear and comprehensive presentations given by the representatives of the Competent Authorities Emiel van Galen and Werner Knöss. Their presentations showed the efforts which had been made to bring forward European harmonisation of homeopathic medicinal products in the past years but also revealed the gaps still existing on Community level.

The major points discussed were: authorisation and registration procedures, legal requirements, mutual recognition and national procedures, anthroposophic homeopathic medicinal products, the role, the objectives and achievements of the HMPWG, the roles and responsibilities of the national competent authorities, the EDQM and the WHO, the guidance documents available and how harmonisation can be achieved. The current status and developments as regards homeopathy and the European Pharmacopoeia were presented by Ms Isabelle Mercier, who showed the constructive work that has been done as well as plans for future work on the further construction of the chapter on homeopathy in the European Pharmacopoeia. Furthermore there were intensive discussions on dossier requirements and requirements for labelling and in-pack leaflets for homeopathic medicines.

In sum, the analysis of the legal and regulatory situation of homeopathic medicinal product given by the representatives of Competent Authorities and by the representatives of industrial organisations were similar, but the perspectives and the resulting key messages were divergent: while industry requested more progress towards harmonisation, the representatives of Competent Authorities encouraged concrete applications in the framework of the Mutual Recognition or Decentralised Procedure in order to create practical examples.



EMEA, London UK

In his conclusion Thomas Lönngren told the audience that as the person responsible for developing the legislation on homeopathic remedies in Sweden fifteen years ago, when he was director of the Swedish Medicines Agency, he had come to the conclusion that there had not been much progress. 'Why complicate a relatively simple matter?', he said. If the institutions would give a mandate and a budget to the EMEA on these issues, then the EMEA would take it on. This is not the case at this moment so 'please member states come together and look for compromises' he concluded.

We look forward to the press release on the EMEA website (www.emea.eu.int) and to the full report in a few weeks time. The PowerPoint presentations of the participants will be made available for our full members and corresponding members as well via the ECHAMP News Ticker.

CONTROVERSIAL PHARMACEUTICAL FORUM 2006: Verheugen wants to improve patient information - but the member states block any change



"...the current situation is unsatisfactory and unacceptable"

Commissioner
Guenter
Verheugen

(PHS) The [Pharmaceutical Forum](#) was established in 2005 to examine the competitiveness of the European pharmaceutical industry and related public health issues. It will take forward some of the most important issues still outstanding from the G 10 Medicines process, in particular patient information, relative effectiveness and pricing/reimbursement. The forum aims to complete its work by 2008. It is expected to propose new legislation on relative effectiveness, pricing and information.

At the first meeting of the high level group (the former G 10) on September 29, chaired by the EU Commissioners Verheugen and Kyprianou, the EU Vice President made the following key and somewhat surprising points:

- Information to patients must be improved because "the current situation is unsatisfactory and unacceptable"
- The legal framework of the early 1990s is "not appropriate anymore", which is tantamount to saying that Directive 2001/83 has not been a success
- Modernization of the legislation has failed
- Member states are asking to revise the section on 'Communication to the patients', which shows a demand for further deregulation.

The EU Commission is now called upon to present a report to the Council and the European Parliament for 2007. One of the objectives is to use this opportunity to redefine a new "framework for information to patients". The public should be consulted by the end of 2006 and "everyone should have the opportunity to contribute," said Verheugen. Even the [Standing Committee of European Doctors \(CPME\)](#)'s President, Dr Daniel Mart pointed out "the lead theme should always be what is the best medication for the individual patient in any given situation."

But there is still a strong controversy. [Jorgo Chatzimarkakis](#) MEP argues that the member states want to block any changes to the status quo of the issues discussed in the PharmaForum. "They want to keep the costs down. They try to avoid any change in pricing because they want to control the costs."

In a letter to the EU Commission, the MEPs will call for the removal of the current patient information ban in [Directive 2001/83/EC](#) on the Community code relating to medicinal products for human use.

Chatzimarkakis has also recently launched the *European life science circle*, "to give chance to those, not members of the pharmaceutical forum, to pre-discuss and pre-assess views on the three topics of the forum". The circle is open to other MEPs, their assistants, pharmaceutical lobbyists and journalists.

This new climate may allow possibilities to bring new input on CAM into mainstream discussions on health policy in the EU, both through the Parliament and directly through the Forum itself.

INSPIRATION AND DYNAMICS AT THE 61st CONGRESS OF LMHI



(FB) The 61st annual congress of the [Liga Medicorum Homeopathica Internationalis \(LMHI\)](#), the international homeopathic medical society (established in

1925), was held this year in Lucerne in Switzerland. Switzerland has a long tradition of homeopathy, and the congress coincided with the 150th anniversary of the [Swiss Association of Homeopathic Doctors \(SVHA\)](#). It was well attended by Swiss homeopathic physicians and veterinarians, and by participants from all over the world. The Congress met the continuing medical education (CME) requirements for doctors, dentists, veterinary surgeons, pharmacists and therapists.



Opening of the LIGA Congress (from left to right) Dr. Clemens Dietrich (Congress President), Dr. Corrado G. Bruno (President LMHI), Dr. Jacques de Haller (President Swiss Medical Association), Patrick K Magyar, Keynote speaker).

A novelty at this congress was the use of [OpenSpace®](#), an on-line conference facilitation tool. Alongside presentations, forum discussions and conventional workshops on topics such as homeopathic case taking and *Materia Medica*, participants could post ideas and topics for discussion on an information wall. When a subject roused sufficient interest, a discussion group was formed under the moderation of the initiator. Feedback was given to the plenary session at the end of the day.

In the morning, prominent keynote speakers set the tone for the conference. Professor Frank Nager,

former Senior Consultant of the Department of Medicine, Kantonspital Lucerne, gave a lecture on the importance of intuition as a bridge between healing technique and the art of healing. Holistic medicine requires a harmonious interplay between the four psychological functions (as defined by C.G. Jung): thinking, feeling, sensation and intuition. A balanced synthesis of discursive thinking and intuition bridges the gap between the healing technique and the art of healing.

Dr. Michel van Wassenhoven, Belgium: "The actual level of scientific evidence about homeopathy for various diseases is already sufficient for the maintenance of homeopathy within medicine. Evidence coming from fundamental research is indisputable, statistically significant and reproducible. Internal evidence (provings followed by clinical verification) is the challenge for the future of homeopathy".



Dr. Ton Nicolai -
President of ECH -
accepting the
Global Politics
Award

Dr. Ton Nicolai, President of the European Committee on Homeopathy (ECH) was awarded the Global Politics Award, a 43 kg statue. This is awarded on an annual basis - this year for the second time - to a homeopathic doctor who has contributed significantly to the political advancement of homeopathy.

The well attended presentations on research (the third day) moderated by André Thurneysen (KIKOM - Bern University) and the simplified registration procedure (the fourth day) by Ms. Dionova of Swissmedic stimulated heated discussions about the controversial way in which the Swiss Ministry of Health has dealt with the PEK study. This is still a live issue in the Swiss CAM community and among the Swiss population, 80% of whom use CAM in one way or another. The decision by the minister of health will be submitted to a referendum. It looks as though the final political word has not yet been spoken.

For more information please [click here](#).

LIGA 2007 - PUEBLA, MEXICO LIGA 2008 - OOSTENDE, BELGIUM

(FB) Preparations are already underway for the next two LIGA congresses - in Puebla Mexico, 7-11 August 2007 and in Oostende, Belgium, Spring 2008.

Mexico has a long homeopathic tradition. It was the first country in the world to grant homeopathy the status of a medical science in 1895 by presidential

decree. The Homeopathic National Hospital and the National School of Homeopathic Medicine subsequently became the first authorised institutions in Mexico. Ortega, a great homeopathic master, was also from Mexico and his fame extends well beyond the Mexican borders. The 62nd LIGA Congress will coincide with the 7th Latin American Congress of Materia Medica and satellite Congresses on Homeopathic Pharmacy and Dental and Veterinary Homeopathy. More information can be found at www.lmhi2007.com.

The 63rd LIGA Congress will be held Spring 2008 in Oostende, Belgium. Regulatory developments are proceeding at quick pace in this European Member State. It is expected that alongside the usual exchange of experiences in homeopathic practice, much attention will be paid to regulatory issues and research. A high attendance is expected since Belgium is at the centre of a number of European Member States (France, UK, Germany and The Netherlands), where homeopathy enjoys great popularity.

ECHAMP BOARD MEETS ASSOCIATED MEMBER BPI



(CH) On 14 September 2006 ECHAMP president Max Daege met the Deputy Director General of Bundesverband der Pharmazeutischen Industrie (BPI) in Germany, Professor Dr. Barbara Sickmüller. Further representatives from BPI were Thomas Brückner, responsible

for homeopathic and anthroposophic medicinal products and Ralph Schmidt, member of the BPI Board and Managing Director of ECHAMP member company, Heel. Max Daege was supported by ECHAMP board members Dr. Gesine Klein and Christa Hebisch.

The German Presidency of the EU offers a useful opportunity to seek closer cooperation and to improve the exchange of information. The main areas for discussion were EU research financing for CAM products, EU-legislation, the implementation of legislation into national law and the work of the Homeopathic Medicinal Products Working Group (HMPWG). The discussion also focussed on possible opportunities for cooperation, which were identified as:

- improved German EU representation
- a possible conference on regulatory issues
- the Dialogue Forum on Pluralism in Medicine
- the 7th Framework Program
- networking in Brussels.

The meeting was constructive and both parties agreed to increase the exchange of information and cooperation at German as well as at European level.

**LEGAL UPDATE:
PERSONAL IMPORTS OF
HOMEOPATHIC MEDICINAL
PRODUCTS IN LITHUANIA**



(JH) Order No. V-793 was adopted by the Lithuanian government on 26 September 2006, amending their Rules on the Supply of Special (Personal) Medicinal Products¹. The initial proposal for the Order ignored a judgment from the European Court of Justice (C-212/03) (*Commission v France*)² by proposing to check personal imports of homeopathic medicinal products for quality, safety, and efficacy.

In this latter judgment, the Court stipulates that a prior authorisation cannot be required for homeopathic medicinal products legally prescribed in the Member State of import and registered in accordance with the special simplified registration procedure in another Member State, unless there is 'good' justification for reasons of health protection. In addition, for (homeopathic) medicinal products which have not been authorised in the country of import, Member States may require a prior authorisation if the procedure is proportionate. One of the implications of this is that, according to the Court, the requirements on consumers are not as heavy as those on commercial players under Article 6 of Directive 2001/83/EC.

ECHAMP successfully supported national initiatives to inform the Lithuanian government that the proposed order did not comply with EU law. As a result, Order No. V-793 now excludes homeopathic medicinal products registered in accordance with the special simplified registration procedure from any check on quality, safety, and efficacy. It remains to be seen whether or not current Lithuanian legislation will comply with judgment C-212/03 with respect to authorised homeopathic medicinal products, depending on the procedure applied by the Lithuanian authorities with regard to personal imports.

For more information see: [Order No.V-793](#)

For more information see: [European Court of Justice](#)

ECHAMP MOVES!

(EVR) ECHAMP is growing! As ECHAMP has started to become more professional, with the recruitment of additional help in the office, and a full time Legal Affairs Officer, more office space was needed. In addition we were unable to stay in our current office for much longer, so we urgently had to find somewhere else.

We are remaining in Brussels, and after a long search, have found a very nice and spacious office, located at Rue Gray in Brussels. This is in the heart of the

'European Quartier', close to the European Parliament and European Commission.

The new office have a meeting capacity of up to 25 people, which means we can organise meetings of the Board of Management and the Working Parties ourselves. This also means that we can offer our members a venue for meetings in Brussels if they need it.

ECHAMP NEW ADDRESS



**RUE GRAY, 100
1040 - BRUSSELS**



: +32 2 649 94 40



: +32 2 649 41 77

Our new phone system allows callers to get straight through to the right person at ECHAMP. Both our phone and fax numbers have changed. We are mailing out our new contact details to all our partners, members and colleagues in Brussels and the different member states. Pictures and directions on how to get to the new office are on the ECHAMP website - please [click here](#).

If you are in Brussels and have some spare time, please do not hesitate to get in touch. You will be most welcome at any time!

ECHAMP Agenda

Nov 23-24	Board Meeting	Berlin Partner Brussels
Dec 6	SG Nosodes	ECHAMP Brussels
Dec 14	WP Public Relations	ECHAMP Brussels

Authors of this issue

FB	Franklin Bech
NDH	Nand De Herdt
CH	Christa Hebisch
JH	Johan Hulshof
PHS	Peter Siebert
EVR	Ellen Van Rompaye

Contact details

ECHAMP EEIG
Rue Gray, 100
B - 1040 Brussels
Phone: +32 (0)2 649 94 40
Fax: +32 (0)2 649 41 77
administration@echamp.be
<http://www.echamp.org>