

Annual Report 2005



Max Daege
ECHAMP President

President's Statement

2005 - Anniversary Year and Year of Implementation

On 10 April 2005 the Homeopathic World Congress of the Liga Medicorum Homeopathica Internationalis (LMHI) at Berlin commemorated the 250th birthday of Samuel Hahnemann, claiming that homeopathy should be part of the regular health care system. ECHAMP, which celebrated its fifth anniversary in Brussels on 9 December 2004, has been working hard to contribute to that goal through its own strengthened network.

By the end of 2004 the Heads of Medicines Agencies (HMA) agreed a formal mandate for the previously non-official Competent Authorities Working Group, creating the Homeopathic Medicinal Products Working Group (HMPWG). This brings recognition to the specific regulatory issues connected with homeopathy, and will hopefully improve the working environment. A symposium organised in February by the European Directorate for the Quality of Medicine (EDQM) resumed the work on homeopathic monographs for the European Pharmacopoeia. ECHAMP supported both develop-

ments by presentations in Rome (2004), Amsterdam and Strasbourg (2005).

The implementation process of Directive 2001/83/EC (amended by 2004/27) in all Member States has also been a central point of focus this year. ECHAMP Guidance Papers assisted the political work at national level, particularly in those Member States which are considering opening up the possibilities for granting a marketing authorisation (Art. 16(2)) for homeopathic medicinal products. Consultation meetings with ECHAMP Members were organised in Copenhagen (for all Scandinavian countries including Norway) and in Madrid.

Meetings with national organisations from countries not represented at European level e.g. Lithuania, led to the creation of a new membership category within ECHAMP: 'Corresponding Partnership'. The ECHAMP Working Group system was further extended, resulting in successful teamwork on nosodes with the practitioners of European Committee for Homeopathy (ECH), the

European Council for Classical Homeopathy (ECCH) and the European Council of Doctors for Plurality in Medicine (ECPM).

The European Court of Justice ruled that Member States are not allowed to impose additional restrictions on top of European requirements (Art. 14(1)). In particular, it considered that dilution ensures the safety of a homeopathic medicinal product. ECHAMP asked questions to the European Commission concerning incorrect implementation by a number of Member States.

Transparency and adherence required

The HMPWG stated on 30 November 2004: "..... transparency and a harmonised interpretation of the legislation is specifically needed for homeopathic medicinal products, because consistency of standards, assessments and good quality decision-making across the EU are in the interest of public health and a prerequisite for implementation of the legislation."

We have therefore requested improved information exchange and the possibility of informal consultation in the process of drafting guidance documents. Most important is that the standards of the European Agency for the Evaluation of Medicinal Products (EMA) are adhered to and that draft documents are published on the website of the Heads of Agencies.

More research needed

Homeopathy definitely hit the headlines in August when the medical journal *The Lancet* announced 'the end of homeopathy'. In the aftermath of the publication the announcement proved to be based on highly biased conclusions. This can only strengthen the plea for more research. Homeopathy and anthroposophic therapies make a significant and favourable contribution to the healthcare sys-

tem (as demonstrated in the Swiss report 'Programm Evaluation Komplementärmedizin' (PEK)), so funding of research projects by the European Commission's Framework Programme VII (FP7) would be money well spent.

ECHAMP's workshop at the European Health Forum in Gastein highlighted research into Complementary and Alternative Medicine (CAM) and the recent developments on homeopathy. This was also the occasion for the launch of the latest ECHAMP brochure 'The Science Base of Homeopathic and Anthroposophic Medicine'.



Lucas von Hebel

For personal reasons Lucas von Hebel was forced to step down as President of ECHAMP in April this year.

He had brought to this role a wealth of experience and clear leadership since our foundation in 1999. We look back with admiration and gratitude at the development and growth of ECHAMP under his guidance.



Dr. Marianne Heger

In 2005 we mourned the unexpected decease of Dr. Marianne Heger, former ECHAMP vice-president. Her name will always be connected with high quality research and the then-innovative International Integrative Primary Care Outcome Study (IIPCOS), which demonstrated trends later confirmed by the PEK report.



Dr. Birka Lehmann

Nand De Herdt

Dr. Emiel van Galen

Prof. Solimene

Dr. Elisabetta Minelli

On 9 December 2004, ECHAMP celebrated its fifth anniversary with a conference and reception in the house of Baden Württemberg in Brussels. The enthusiastic response by 120 participants from 14 different countries was symptomatic of the position ECHAMP has reached as a leading voice on homeopathic and anthroposophic medicinal products for the decision makers at European level and agencies.

The afternoon conference was moderated by Nand De Herdt, General Secretary of ECHAMP. Dr. Birka Lehmann, representing the European Commission, DG Enterprise and Industry and Dr. Emiel van Galen from the Dutch Medicines Evaluation Board gave their view on the legal environment following the implementation of the amended Directive 2001/83/EC in the EU Member States and the position of The Netherlands in putting the EU rules into practice, zooming in to regulatory consequences and the future

Mutual Recognition Procedure for homeopathic medicinal products.

The second part of the conference dealt with the specific involvement of the University of Milan and the Region of Lombardy creating an open door for CAM. Prof. Dr. Umberto Solimene (World Health Organisation (WHO) Collaborating Centre for Traditional Medicine, University of Milan) informed the audience of the expected report on the evidence base of homeopathic medicinal products which is currently undertaken by WHO. Dr. Elisabetta Minelli, representing the regional government of Lombardy, spoke about the decision of the regional government to sponsor research activities (studies, round tables, working groups and consultation progresses), sometimes in close co-operation with WHO.

All presentations ignited an intensive discussion in which the international audience - members and guests - took an active part.

The afternoon conference was closed by Max Daege, ECHAMP President of the Membership Assembly. He officially opened the birthday celebration by offering the participants of the conference a mini Zen Garden as a tool of reflection and inspiration. He also presented the ECHAMP Tool Box with information brochures. Since then five brochures have been published including Homeotherapy, Medicine for Children and the Science Base of Homeopathic and Anthroposophic Medicine.

The reception offered the participants from European and national institutions and agencies the chance to network and exchange ideas on the past and the future of homeopathy and anthroposophic medicinal products in the European Union.

ECHAMP Membership Assembly 2005



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For an EEIG the membership assembly is an annual obligation. For the past two years, ECHAMP has combined its membership assembly with a workshop and social event, allowing members and partners to deepen their understanding of European issues and to network in a casual and friendly atmosphere.

In 2005 the membership assembly was organised in London, attracting more than 50 participants from 14 different countries to join our meetings.

The evening programme, kept secret until the last minute, took the participants on a

guided double-decker bus tour through the City to the London Eye and the Barber-Surgeons' Hall where dinner was served in a historical setting.

The Workshop

'Designing the Regulatory Future of Homeopathic and Anthroposophic Medicines: After the Review - A strategy for the implementation of the new European legislation into national law'.

The workshop program offered an in-depth study of recent developments in the legal and regulatory environment for homeopathic and anthroposophic medicinal products.

Presentations on the regulatory environment were given by Dr. Sue Harris, Head of Unit of the Medicines and Healthcare Related Products Regulatory Agency (MHRA) of the United Kingdom, Penny Viner for British Association of Homeopathic Manufacturers (BAHM) (United Kingdom) and Ir. Bernard Mauritz for Neprofarm (the Dutch union of the pharmaceutical industry of self-care medicines and health products). The conclusion was that there is much room for interpretation, Member States have a wide margin for their own interpretation and policy and the road to harmonisation is still a long one.

The Membership Assembly

Six new Full Members were unanimously accepted as well as three Corresponding Members and two Associate Members.

The speakers' program this year was completed by a presentation on the present status of research on effectiveness of homeopathic medicinal products by guest speaker Dr. Peter Fisher, Director of Clinical Research of the Royal London Homeopathic Hospital.

Working Parties More than 50 meetings in 2005



Nosodes Working Party

The evolution is in the action. The output from the Working Parties (WPs) in 2005 demonstrates an impressive quantity of quality work and a valuable contribution to the credibility of ECHAMP as a partner in legislative and regulatory affairs.

The Research WP developed a proposal to support the ECHAMP Implementation Guide, paving a possible way for the introduction of

a system for marketing authorization. This document was offered to Member State policy makers through national manufacturers' organisations.

The Common Technical Document (CTD) Subgroup this year continued designing specific regulatory solutions for homeopathic medicinal products on various topics and regulation levels. In October preliminary

comments were submitted on the new draft of the HMPWG on Module 3 of the CTD.

The Safe Concentration List WP elaborated on the safety issues connected with potencies under 1:10.000 and mother tinctures. On the one hand, present legislation curbs the existence of many products already on the market with a long-standing safety record. On the other hand the relevant article in the Directive does not provide for the safety as intended by the legislator. A new perspective on safe concentrations might create new evidence which could make further fine tuning of present legislation possible. The preliminary results have been submitted for an opinion by an independent toxicological expert.

The Joint EU Working Group on Nosodes also includes delegates from ECH, ECCH and

ECPM. The group produced a comprehensive document in response to the invitation by the HMPWG to comment on the "Points to Consider on the Safety of Homeopathic Medicinal Products from Biological Origin". Constructive proposals were made introducing realistic techniques of risk assessment which should replace a system of rigid demands potentially resulting in the eradication of a group of medicinal products which used to play (and still plays) a significant role in homeopathy.

The CEEC Member States WP effectively supported members in resolving regulatory issues. Visits were paid to the Polish agency and a fruitful exchange took place in the meetings harmonising a number of regulatory interpretations.

The Monographs Sub Group submitted comments on EDQM draft monographs on: *Amanita phalloides* for homeopathic preparations PA/PH/Exp HOM/T (03) 22 ANP, *Pulsatilla vulgaris* for homeopathic preparations PA/PH/Exp HOM/T (03) 25 ANP and PA/PH/SG (04) 117 ANP: 5.1.7 VIRAL SAFETY.

Working Party specialists took part in the HMPWG hearing in Amsterdam and other clarifying events in the legislative and regulatory field.



CEEC Member States Working Party

EDQM Symposium on Homeopathy

Monographs for the European Pharmacopoeia

In February this year ECHAMP was invited by EDQM, together with other industry and pharmacy associations to attend the Symposium of the European Pharmacopoeia 'Quality of Homeopathic Products in the New European Legislative Framework'. Presentations were given by representatives of the European Commission, the European Pharmacopoeia Commission and the Homeopathy Working Party of the European Pharmacopoeia. Regulatory authorities from Member States gave their points of view on the pharmacopoeia work and specific regulatory policy in the own country. One presentation specifically dealt with the raw materials of human and microbiological origin (nosodes). In the last session of the symposium presentations were given by the pharmacists' and industry associations, ECHAMP, the Comité International des Pharmaciens Homéopathes (CIPH), and the International Association of Anthroposophic Pharmacists (IAAP). All the representatives expressed the wish that the Homeopathy Working Party of the European Pharmacopoeia should continue its work.

Homeopathic monographs are a very important tool for our members and in this respect ECHAMP appreciates the work and the transparency shown by EDQM concerning the drafting of homeopathic monographs.



The special ECHAMP subject group 'Pharmeuropa' always prepares the industry's points of view on the drafts published in Pharmeuropa.

Industry is in favour of the continuation of work on the European Homeopathic Monographs to set high quality standards. Pharmacopoeia monographs should reflect the quality of the starting materials in the best possible way, show how the products (the mother tinctures and the dilutions) should be manufactured and how the constant quality of the manufactured product can be demonstrated.

In general the basic principles of homeopathy as well as the long experience of this specific therapeutic approach should be considered and be integrated in the scientific character of the work on monographs.

During many decades two homeopathic pharmaceutical traditions have been developed reflecting the reality in two important Member States: France and Germany. They are laid

down in two official national pharmacopoeias, the French and the German Homeopathic Pharmacopoeia. ECHAMP believes that the monograph work of the European Pharmacopoeia in this field should take both traditions fully and equally into consideration. This will make it possible to have clear monographs unambiguously describing the starting material, the manufacturing methods and the specifications of the homeopathic products. Only in this way can the specifications be realised in such a way that quality and reproducibility can be guaranteed.

Based on these principles and aiming for good quality as its highest priority, ECHAMP is very much in favour of continued work on homeopathic monographs within the European Pharmacopoeia. As the European association of manufacturers, we will keep doing whatever is necessary in this respect, continuing our co-operation with institutions and other associations to contribute to the realisation of this work.

Complementary medicine on the European stage

Workshop at the European Health Forum 2005



Opening of the European Health Forum



ECHAMP Workshop

The eighth annual European Health Forum took place in Bad Gastein (Austria) 5-8 October under the title 'Creating a better future for health in Europe'. For the first time in its history a part of the programme was dedicated to CAM with a workshop organised by ECHAMP. The workshop's title was 'Complementary Medicine - an efficient and safe contribution to patient satisfaction?' and the subject: 'Could more than 100 million European citizens be wrong? - Developments around the evidence base of homeopathy'. The workshop was attended by more than 40 people and generated lively discussion.

In addition, a press conference offered the opportunity to raise extra attention and media coverage on the various subjects. Interviews were broadcast on Austrian radio and television. The Forum proved to be an important event to bring CAM, and homeopathy in particular, to the attention of policy makers. "Until now there have been problems with the

political willingness to legally implement generally approved directives in the individual member states," says Daeye. In this respect the question to the EU health commissioner Kyprianou was asked: "When is the Commission finally going to respond to the request of millions of EU citizens?"

Presentations at the workshop were given by Prof. Dr. Stefan N. Willich (Director Institute for Social Medicine, Epidemiology & Health Economics, University Hospital Charité of Berlin, Germany) on cost effectiveness of acupuncture and homeopathy, Dr. Peter Fisher (Clinical Director and Director of Research of the Royal London Homoeopathic Hospital) on the efficacy profile of homeopathy, Dr. Maurizio Italiano WHO Collaborating Centre for Traditional Medicine and CAM, University of Milan) on the role of the WHO Collaborating Centre in the integration of complementary medicine in the regional healthcare system of Lombardy,



Dr. Maurizio Italiano



Dr. Ton Nicolai



Prof. Dr. Stefan Willich



Dr. Peter Fisher

Italy and Dr. Ton Nicolai (president of the European Committee for Homeopathy (ECH)) on patient satisfaction with homeopathy and CAM in general asking for more public funding of research projects.

ECHAMP Brochures



In 2005, two new brochures were added to the ECHAMP "Toolbox". "Medicine for Children" highlights the effectiveness of homeopathy and anthroposophic medicine in pediatrics. The latest brochure is entitled "The science base of homeopathic and anthroposophic medicine". This gives a concise summary of a broad range of homeopathic research with an emphasis on the developments in different areas of science: from physics and (veterinary) medicine to health economics. Its aim is to provide a journalist approach of the subject for readers with little time.

The updated portrait of ECHAMP members also demonstrates the quick growth of our Association.

Toolboxes and individual brochures can be ordered from the ECHAMP Office.

DVD on Complementary Medicine

New is a 7 minutes DVD entitled 'Complementary Medicine: The healthy choice of more than a hundred million patients and tens of thousands of practitioners in Europe'. This DVD has been launched as a joint initiative between 12 organisations active in this field. A free copy can be ordered from the ECHAMP Office.

ECHAMP NEWS

ECHAMP NEWS provides a brief monthly update by e-mail on European and other international issues relating to homeopathy and anthroposophic medicinal products. It provides simple summaries of key issues with contact details for follow up information. If you would like to receive ECHAMP NEWS directly, please register by sending an e-mail to the office of ECHAMP (office@echamp.be). Alternatively all back issues can be found on our website.

www.echamp.org

If you would like information about pharmaceutical legislation in the EU Member States, more details on homeopathic and anthroposophic medicinal products or to learn more about how our association is organised, please visit our website!

Editorial team for the Annual Report 2005:

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