ECHAMP

Annual Report 2007

2007: Will Better Communication Lead to Better Legislation?

President's Statement: Max Daege

2007 has seen progress in the regulatory environment for homeopathic and anthroposophic medicinal products in the EU, in terms of a better environment for communication with the authorities, created by the German and Portuguese Presidencies. During the first half of the year, Germany led an initiative for a new administrative structure for the Homeopathic Medicinal Products Working Group (the HMPWG) of the Heads of Medicines Agencies (HMA). In Lisbon in July, the HMA officially adopted Rules of Procedure including a mandate of ten rules governing this European forum on regulatory and scientific expertise regarding the assessment of the quality and safety for homeopathic medicinal products for human and veterinary use in the Member States.

The HMPWG will now have a president for a term of three years; it can invite experts and create sub-working groups. The first president was elected in November 2007 at the plenary meeting of the Working Group in Lisbon: Dr. Emiel van Galen, who represents The Netherlands in the HMPWG. The rotating vice president seat will be accorded to the Member State with the EU Presidency, which will be in charge of organising the half-yearly plenary meeting of the HMPWG. This improved working environment should also help pave the way for much needed improvements in the EU legislation that governs these products and its harmonised interpretation and application. ECHAMP looks forward to an improved and fruitful cooperation with this newly structured working group of the competent authorities.

ECHAMP hopes that the new organisation will be able to speed up the construction of a strong, complete and appropriate regulatory framework for homeopathic and anthroposophic medicinal products in the European Union. This will be needed in order to make 'exponential progress' in the several procedures foreseen in Directive 2001/83: simplified registrations in accordance with Article 14 still to be done in many Member States, mutual recognition of simplified registered products, and marketing authorisations in accordance with Article 16(2), for which a more harmonised approach is needed amongst the Member States.

2007 also saw the first legislative steps in EU health policy to recognise complementary medicine (CAM), actively accompanied by ECHAMP. The European Parliament gave its approval to the EU public health programme and a specific reference to 'recognise the importance of a holistic approach to public health and take into account … complementary and alternative medicine.'

In addition, the EU Framework Programme for Research and Technological Development from 2007 to 2013 offers access to EU funding in the field of complementary medicine. In this 7th Framework Programme there is a small but specific reference to complementary medicine in its health section and in the provisional Working Programme. However, it will be quite a challenge for the European CAM research community to participate in one of the calls for applications for EU funding.

2007 has also been a year of increased demand for a more integrated concept of medicine. In April the European Public Health Alliance (EPHA), a network of European non-governmental health-concerned organisations including patients and doctors, held an important international conference in Bratislava. The policy recommendations highlighted that 40-60% of the EU population makes use of CAM (source WHO). The European Commission - represented by Bernard Merkel - was addressed to give attention to an integrated health care system which would be beneficial for patients as well as for Member State health budgets.

The same aim was on the agenda of the first European Dialogue Forum for Pluralism in Medicine. This time medical doctors from the conventional and complementary medicinal field represented by renowned researchers and university teachers brought a German initiative to Brussels in order to demonstrate to health politicians the need for a

broader dialogue with the aim of bringing the benefits of both disciplines together and eventually arrive at one medicine that is directed toward the patient as a whole.

In this context, the secure and full availability of homeopathic and anthroposophic medicinal products remains ECHAMP's main priority. Despite all good will by Commissioner Verheugen, there is increased concern that the present EU regulation is not adequate to promote harmonisation, free access and full availability for these products. In February 2007, a high ranking ECHAMP delegation expressed these concerns to the Commission and Members of the European Parliament. This dialogue will continue and ECHAMP will focus decidedly on a better regulation and present concrete proposals in the first half of 2008.

The notably increased support from our members has helped to strengthen our organisation in 2007. On behalf of the entire Management Board, the office team and the assistants, I thank all members for this support and especially those delegates who have contributed so actively with their expertise in the Working Parties and Subject Groups.

Highlights from Some Member States

Lithuania ready to accommodate therapeutic indications

During the second half of 2007, ECHAMP was able to provide support to Lithuanian members and stakeholders, especially regarding the adoption of rules and guidelines to facilitate the full implementation of a national legislation for granting marketing authorisations for homeopathic and anthroposophic medicinal products with a therapeutic indication (Art. 16(2) option in Directive 2001/83/EC). An interesting exchange of views and information took place at the offices of the Lithuanian Health Ministry in Vilnius in July. Further progress has been made and the new legislation is expected for the near future.

ECHAMP Group Spain successful in working towards a new medical law

The Spanish ECHAMP members are united in a national Working Group which has been successful in accompanying the law making process for homeopathic and anthroposophic products in that country. A continuous and constructive dialogue with the Ministry of Health lasted until the recent official release of the final draft of a Royal Decree on Medicinal Products including those of homeopathic character. For a large number of products currently on the Spanish market as notified products, ECHAMP Spain expects a 'normal' transition from the present situation to that of fully registered products according to the Simplified Scheme within a time frame of five years. This will be the case as well for those products which have a therapeutic indication and which can apply for a homeopathic marketing authorisation according to the adapted Spanish national regulations (Art. 16(2) option in Directive 2001/83/EC).

Second Nordic meeting discusses freedom for CAM

In October, ECHAMP Board Members visited Stockholm for a series of meetings with key stakeholders in the field of homeopathic and anthroposophic medicine in the five 'Nordic countries' - Denmark, Sweden, Finland, Norway and Iceland, as well as with a number of Swedish politicians and civil servants. The visit was facilitated by the Nordic Cooperation Committee for non-conventional Medicine (NSK), the Nordic CAM umbrella association. The main aim was the exploration for better legislation to also cover homeopathic and anthroposophic medicinal products with a therapeutic indication.

After high level political contacts ECHAMP representatives found reason to believe that in the Nordic countries - including Sweden - the future bodes well for the adoption of EU-wide recognised standards for CAM in health politics.

ECHAMP: Towards a Better Legal and Regulatory Environment

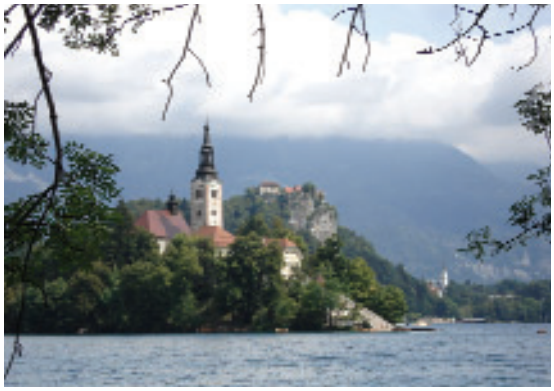
Report from General Secretary, Nand De Herdt

A review of 2007 demonstrates that ECHAMP continues to make progress towards increased professionalism. The process of professionalisation of the association started in Vienna in 2006, aiming at improving the quality of ECHAMP's communications, activities and statements, and also the exchange with decision makers and competent authorities.

The field of regulatory affairs has been the highest priority in our activities. The Bonn workshop in early 2007 discussed how to build a more appropriate regulatory environment. During the year we had the opportunity to attend several important meetings of competent authorities such as BFArM in Dialogue - Europe in Bonn, the WHO consultation meeting on the WHO guidelines on Quality for Safety of Homeopathic Medicines in Milan and the Workshop on Homeopathy during the European Directorate for the Quality of Medicines (EDQM) Conference in Strasbourg. Reports on all these events were published in ECHAMP News during the year.

Based on numerous contacts of our members with their national medicines agencies, in some cases already preparing first steps into Mutual Recognition Procedures, and based on interesting individual exchanges we have had with HMPWG members, we have increasingly been able to identify and understand the major difficulties for our members in the current regulatory framework.

Regulatory affairs will be the major focus for the workshop at our next Membership Assembly, to be held in April 2008 in Bled, Slovenia, the first CEEC Member State to have the EU Presidency. Specifically, we intend to work on proposals for better regulation for homeopathic and anthroposophic medicinal products. This is in line with the policy of the European Commission promoting legal and regulatory improvements for the European pharmaceutical industry.



Bled, Slovenia

ECHAMP's proposals - to be presented in Bled in April 2008 - will be based on the experience of its members since the first homeopathic directive came into force in 1992.

We look forward to meeting all of you at Bled for the association's most important event of the year.

Participants of the WHO Consultation Meeting on the WHO Draft Guidelines on Quality for Safety of Homeopathic Medicines (Milan, 25-27 June 2007)

Membership Assembly 2007: Focused on 'Legal and Regulatory Affairs'

The yearly ECHAMP members' meeting and Membership Assembly 2007 took place in Bonn on the 23rd and 24th of April.

Meeting in Germany during the German EU Presidency, ECHAMP was honoured by the patronage of the German Minister of Health and Social Affairs, Ulla Schmidt. Dr. Klaus Theo Schröder, the German Secretary of State to the Minister of Health, gave the opening speech in which he expressed the belief of the German government that homeopathic and anthroposophic medicines should be fully available to all Europeans. He also stressed the German commitment to take concrete steps towards a harmonised European market for these products.

The Secretary of State was followed by Dr. Werner Knöss - at that time the chairperson of the Homeopathic Medicinal Products Working Group (HMPWG) at the Heads of Medicines Agencies (HMA) - who gave an excellent, clear and well-documented presentation on the regulatory situation of homeopathic medicinal products in the EU and Germany.

On the first afternoon, the participants had the choice of two parallel session workshops

- The optimum future legal and regulatory environment for homeopathic and anthroposophic medicines in the European Union;
- How to communicate effectively with decision makers and authorities in Brussels and the Member States.

The outcome of the first workshop, in which ECHAMP members gave valuable feedback regarding legal and regulatory problems, led to the initiation of a project to make legislation and regulation more efficient and better suited to the specific characteristics of homeopathic and anthroposophic medicinal products. In the second workshop two experienced guest speakers presented their approach on how to communicate efficiently with decision makers and authorities in Brussels and in the Member States. The members' meeting was concluded with lively discussions on ECHAMP's priorities and concerns for the coming months and years and on different ways to bring the messages across.

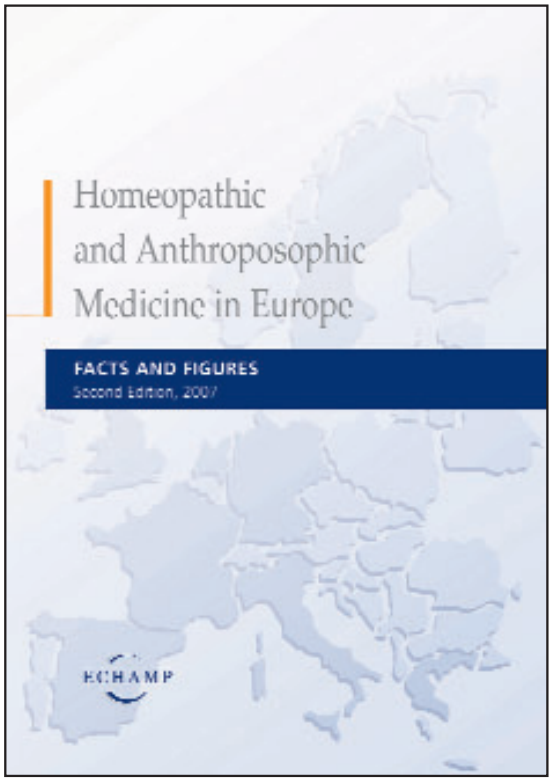
The Membership Assembly, which took place on the second day, was chaired by Dr. Walter Witt of DHU. He announced a further increase of the ECHAMP membership. Two new full members, two new associated members and one new corresponding partner joined ECHAMP in 2007 *(see page 8)*.

ECHAMP's tenth Membership Assembly marked the end of an era for Lucas W. von Hebel, co-founder and first ever President of ECHAMP. To commemorate Lucas' career, which included many years of active involvement in the European herbal industry and six years as ECHAMP President, ECHAMP organised a surprise farewell party. Lucas von Hebel was addressed in a farewell speech by Prof. Dr. Konstantin Keller and in short cordial farewell words by Prof. Fritz Kemper and Dr. Bernd Eberwein.

Max Daege thanked Lucas for his excellent work. Lucas was subsequently nominated by the Board of Management as first Honorary President of ECHAMP.

From left to right:
Nand De Herdt, Max Daege, Prof. Fritz Kemper, Dr. Bernd Eberwein, Lucas W. von Hebel, Prof. Dr. Konstantin Keller

Homeopathic and Anthroposophic Medicines in Europe Facts and Figures (Second edition, 2007)



In November 2007 ECHAMP launched an update of the first Facts & Figures brochure, originally published in 2003. Since sales and marketing data of homeopathic and anthroposophic medicinal products are not collated systematically by the usual market research agencies, this project was outsourced to a third party. Based on merged data provided by ECHAMP members and open sources, a well documented 106-page booklet was presented to the press and mailed to the media, politicians and stakeholders.

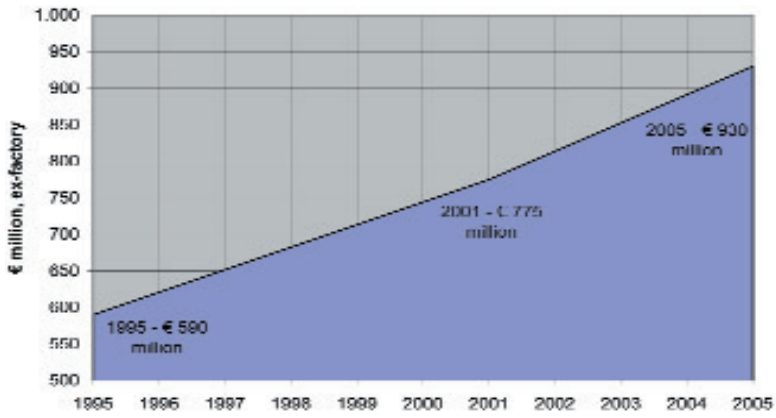
The market for homeopathic and anthroposophic medicinal products is now worth €930 million. Between 1995 and 2005, it increased by 60%, or more than 5% per year on average. Consumers across Europe spend an average of €4 a year each on these products, which account for approximately 7% of the European non-prescription pharmaceutical market, or 1% of the total European pharmaceutical market.

This growth comes despite the fact that hundreds of products have been withdrawn from the market since 2003 due to the increasingly severe requirements imposed on the industry by national Medicines Agencies, and their inflexible interpretation of European legislation. *Homeopathic and Anthroposophic Medicine in Europe: Facts and Figures (Second Edition, 2007)* provides new and comprehensive information on the use, history, legal status and position in national health care systems of homeopathic and anthroposophic medicinal products in Europe, giving a unique and valuable insight into the industry of HAMP.

The publication includes:

- a profile of the industry in Europe, including market growth and detail on key markets with a special focus on the new CEEC Member States
- key historical data and a market by market history of the development of the use of homeopathic and anthroposophic medicinal products demonstrating the historic roots of homeopathy throughout Europe
- a summary of the legal and regulatory situation for these products in each country including a statement on the practical situation
- the status of complementary medicine within the health care systems of each country
- individual country profiles for 29 countries, summarising the history, regulatory situation and status of CAM with key contact details
- links to key agencies.

The new expanded version of the 'Facts & Figures' is a valuable source of information. It confirms that there is still a long way to go before we can speak of a harmonised market.



Sales of HAMP in the EU (Source ECHAMP 2007)

Highlights from the Working Parties

Pharma-regulatory affairs (5 subject groups)

Regulatory affairs

2007 has been extremely busy for those working in the Regulatory Affairs (RA) units of member companies in terms of company applications. The only really new RA items occurred in autumn 2007. The Subject Group Regulatory Affairs (previously SG-CTD) met to discuss draft legislation, new legislation and guidance on variations, consultation by the European Commission, Part II of the CTD, Regulation 1901/2006 on Medicinal Products for Paediatric use and readability testing.

Mutual recognition procedure/ Decentralised procedure (MRP-DcP)

This year the Subject Group MRP/DcP focussed on the legal framework as well as on practical aspects like suitable Reference and Concerned Member States for a first project. To date there is no practical experience with mutual recognition within the participating companies of the subject group. Strategic planning for companies is difficult due to lack of information on fees for MRP/DcP in some countries and because of Member States' different views on acceptability of existing national registrations as a base for mutual recognition procedure.

Safe concentration list

There were no new initiatives nor requests from the competent authorities in this field in 2007. Based on the preparation work in 2006 we delivered to the HMPWG of the HMA last comments on the two Points to Consider documents dealing with safety assessment. The final drafts of these documents have now been published on the HMA website. We also gave our point of view on how to deal with the provisions of Article 69 of Directive 2001/83 as a positive tool of giving product information on the labelling or the leaflet as required for the safe use of registered homeopathic remedies.

Pharmacopoeia

In view of the working program of the European Directorate for the Quality of Medicines' new working party on raw materials and homeopathic stocks (Group HOM), the Subject Group on pharmacopoeial affairs was refounded in May 2007. The former subject group had been working since 2000, and commented on EDQM draft monographs after their publication in Pharmeuropa. Comments to EDQM have been distinct: "German" comments and "French" comments. Consultations with national pharmacopoeia committees took place. Though this way of acting was reactive, ECHAMP has gained high respect from EDQM. The newly reformed group will focus on achieving a solid consensus on the quality standards to be published in the European Pharmacopoeia by sufficient proactive laboratory testing in order to cope with the deadlines of EDQM.

Nosodes

In spring, it became known that regulatory initiatives could be expected under the German presidency. The ECHAMP comments on the draft guidance paper on Biologicals were brought up to date and resubmitted to the HMPWG.
The EU Joint Working Group on Nosodes, which includes participants from ECH, ECCH and ECPM, prepared for an informal hearing organized by members of the HMPWG to collect information and explore possibilities to come to practical solutions. A small editorial group was set up to start the preparation for a scientific regulatory publication on nosodes. The position of this product group containing remedies based on provings referred to by Hahnemann himself becomes increasingly precarious. Unless practical solutions are developed it can be feared that a grey market will develop which will be outside the control of regulators.

Pharma-political affairs

In early 2007 four CEOs of major ECHAMP member companies visited the European Parliament and the European Commission, meeting with three members of the Parliament and a staff member of the cabinet of Commissioner Verheugen.

Good cooperation with our corresponding members helped ensure the inclusion of complementary medicine (CAM) in the two major programmes of the EU, the 7th Framework Programme for Research and the Community Health Programme, both running from 2007 to 2013.

In 2008 the Working Party will start to prepare for 2009, when there will be elections of a new Parliament and a new Commission.

Central and Eastern European Countries (CEEC)

In 2007, the Working Group's activities were related to the so-called updating, the commitment of the new Member States to bring their products into line with EU standard. This running update is a demanding task both for the companies involved and the agencies. Whereas in Poland company specific issues required individual approaches, the situation in Lithuania made a visit to the Lithuanian Health Authorities by a high ranking ECHAMP delegation necessary; this had a promising outcome.

Legal affairs

A number of legal problems with regard to homeopathic and anthroposophic medicinal products have to be dealt with in Europe. In order better to identify these and support ECHAMP member companies in solving problems that are caused by legal rules and administrative practices on EU and national levels, a Legal affairs "kick-off" meeting was called in January 2007. 18 participants from 7 EU Member States accepted the invitation and made the meeting a successful first step towards a closer cooperation.

One of the legal issues that caused quite some attention in 2007 was an important decision of the European Court of Justice (ECJ) concerning anthroposophic medicinal products (Case-84/06).

Public relations and communication

The plan for 2007 was ambitious. In order to be able to address the various audiences in the right way much new material had to be produced. *Homeopathic and Anthroposophic Medicine in Europe: Facts and Figures (Second Edition, 2007)* will be an important source of information in our communication with European and national politicians and policy makers.

As a service to the members an up-to-date press pack was prepared with summary sheets and a set of images, enabling users to respond quickly to issues regarding homeopathy and anthroposophic medicines. Finally the WP-PR rendered many services and support back stage. A creative year for a small and professional team.

Membership

Two new members were welcomed to ECHAMP in Bonn in April: Dr. Maria Dancheva Co. (Bulgaria) and MITELA Ltd. (Lithuania). The national manufacturers associations from Denmark (Dansk Homøopatisk Selskap) and Sweden (LFfH - Leverantörsföreningen för Homoepati och annan Komplementärmedicin) joined as associated members, as well as the Permanent Committee of Consensus and Coordination for CAM in Italy, our second Corresponding Partner. ECHAMP now has 52 Full Members, 12 Corresponding Members, 11 Associated Members and 2 Corresponding Partners from 17 different Member States. The updated list of our members is on the ECHAMP website www.echamp.org.

ECHAMP: 52 Full Members in 17 Member States

ECHAMP Resources

ECHAMP News is published eight times a year, and provides a useful round up of legal and regulatory developments affecting homeopathic and anthroposophic medicinal products, as well as updates on major events in this field. To receive copies of this free publication, please subscribe by sending an e-mail to administration@echamp.be.

ECHAMP has developed new information for the press. For a copy of our press pack including background information on Homeopathic and Anthroposophic Medinial Products and photographs for use by the media, please e-mail media@echamp.be.

ECHAMP E.E.I.G.
European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G.

Rue Gray 100
B - 1040 Brussels
Tel.: +32 2 649 94 40
Fax: +32 2 649 41 77
office@echamp.be
www.echamp.org