



ECHAMP e-News December 2011

■ **Editorial** Page 2

■ **Pharma package: an update**

Significant progress has been made in recent months on the Pharma package, with new legislation published for the first two of the three proposals. The provisions for pharmacovigilance will introduce possibly one of the biggest changes in the legal framework for human medicinal products of the last twenty years. ECHAMP President Nand De Herdt provides a round-up of developments in the field of EU pharmaceuticals and their implications for homeopathic and anthroposophic medicinal products. **Page 2**

■ **European Commission programmes - the added value of complementary healthcare**

A number of EU public health initiatives may offer scope to raise the profile of homeopathy and complementary medicine at EU level. Christine Marking, ECHAMP public affairs consultant, reports on the progress of a number of Commission programmes: 'Health for Growth', a new EU health programme (2014-2020), Horizon 2020, the future EU funding programme for research and innovation, and the Active and Healthy Ageing Partnership, stressing the need for the CAM community to make its voice heard. **Page 5**

■ **A new report in English supports effectiveness of homeopathy**

A comprehensive report into the effectiveness, use, safety and cost effectiveness of homeopathy is now available in English. 'Homeopathy in Healthcare' presents the results of the first multi-disciplinary review (Health Technology Assessment) into homeopathy; it concludes that 'there is sufficient evidence for the clinical efficacy of homeopathy and for its safety and economy compared to conventional treatment. **Page 7**

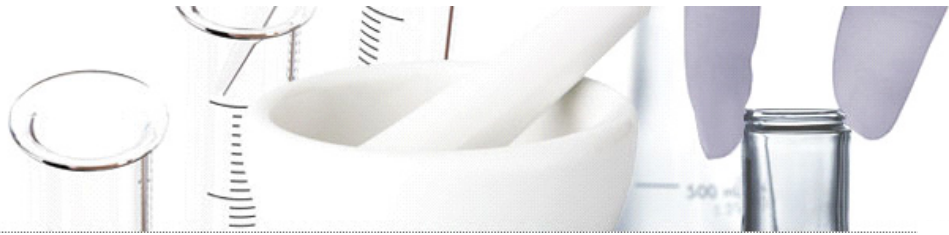
■ **A triumph for homeopathy in Sweden**

Unlike all other EU Member States except Slovenia, doctors in Sweden have till now been denied the right to prescribe homeopathic medicines. However, a recent court decision, ruling the appeal by one doctor, may change this situation. Dr Anders Petterson describes his personal struggle over the past few years to give doctors the freedom to prescribe homeopathic remedies. **Page 8**

■ **An interview with Enid Segall**

Enid Segall, President of the European Federation of Homeopathic Patients' Associations and Chairman of the Friends of the Royal London Hospital for Integrated Medicine talks to E-news editor Karen Chapman about the importance of patient pressure to highlight the benefits that European citizens derive from using homeopathy and the need to integrate homeopathy and CAM in EU health policy. **Page 9**

■ **Calendar** Page 11



Editorial



Some experts of the Chinese language claim that the Chinese symbol for the word 'crisis' is a composition of the two Chinese words 'danger' and 'opportunity'. The first two of these words, 'crisis' and 'danger,' are increasingly prevalent in many discussions and articles, in particular on the European Union. In this issue of the ECHAMP E-News we prefer to focus on the third word, 'opportunity'.

Indeed, in addition to the hopeful vision of the patients of homeopathy, and the successful battle of one Swedish homeopathic doctor, this issue of the E-News reflects the confidence that there are now major opportunities to give reliable complementary healthcare the place it deserves in a modern society. I very much hope that the decision makers will show increasing interest for the added value complementary medicine can bring in terms of effectiveness, cost-effectiveness and better health for European citizens. Enjoy this issue!

Nand De Herdt
President of ECHAMP

Pharma package: an update

Significant progress has been made in recent months on the so-called Pharma package, launched by the European Commission at the end of 2008, with new legislation being published for the first two of the three proposals that were tabled together in the field of pharmaceuticals:

- Improving patient protection by strengthening the EU system for the safety monitoring of medicines (**pharmacovigilance**)
- Tackling the growing issues of counterfeiting and illegal distribution of medicines (**falsification**)
- Enabling citizens to have access to high-quality information on prescription-only medicines (**information to patients**).

Pharmacovigilance

Legislation published, implementation ongoing

In addition to a number of recent drug scandals, there were good reasons for the decision makers to speed up the work on this item. The Commission includes the following figures in its summary of the impact assessment:

- 5% of all hospital admissions are for Adverse Drug Reactions (ADRs)
- 197,000 deaths per year in the EU are caused by ADRs
- the total societal cost of ADRs in the EU is €79 billion per year.

The same summary suggests rather limited savings to EU society: between €237 million and €2.4 billion per year once the measures are fully operational with anything between 591 and 5,910 lives saved across the EU each year.

All the stakeholders will be involved to make the system workable and efficient: the patients, the healthcare professionals working with medicinal products, the regulatory authorities at European level (**European Medicines Agency**), the national medicinal products agencies in the EU and EEA countries, the pharmaceutical companies and the import and distribution companies.

ECHAMP E-news of March 2011 reported on the community legislative process on pharmacovigilance up to the publication on 31 December 2010 of **Regulation N° 1235/2010** and



i continued Pharma package: an update



© European Commission, 2011

Directive 2010/84/EU in the Official Journal of the European Union. The Member States now have until July 2012 to implement the new Directive, from which date onwards the Regulation will also fully apply.

Member States will adopt a series of implementation measures so as to harmonise the performance of the new pharmacovigilance activities introduced by the legislation. These measures supplement the essential details of the new pharmacovigilance system with the more technical details to be observed by marketing authorisation holders, national competent authorities and the **European Medicines Agency** in the daily practice of applying the new provisions.

In a consultation exercise that ended on 7 November 2011, the European Commission sought the views and feedback of stakeholders on the scope and content of the implementation measures under consideration and their contributions have been published on the Commission website. It also published a call for members of the new Pharmacovigilance Risk Assessment Committee (PRAC), which is planned to be operational from July 2012. A further stakeholder consultation took place on 22 November 2011. The Commission is now proceeding with the finalisation of the guidance after consulting the Member States through the advisory **Pharmaceutical Committee**.

The Commission is envisaging a further tightening of the legislation on pharmacovigilance through the recently released amended proposals on information to patients (see below). These foresee in particular an automatic referral at European level of specific

serious safety issues with nationally authorised products, so that they can be assessed and addressed in all the Member States where the medicinal product is authorised; and to avoid the case whereby a voluntary withdrawal of a marketing authorisation or product by the holder might lead to safety issues not being addressed in the EU.

The **European Medicines Agency** is playing an important role in the preparation of the guidance environment for the new pharmacovigilance legislation and has already published first extensive **strategy and policy documents**. It will also play a major role in the management of data and information, and its 'Pharmacovigilance and Risk Management' unit is very active. It is obvious that much resource will be needed by the agency to organise these pharmacovigilance provisions, possibly one of the biggest changes in the legal framework for human medicinal products of the last twenty years.

Nevertheless, the legislation does not really bring any added value for homeopathic and anthroposophic medicinal products since existing pharmacovigilance data for these products show very limited adverse drug reactions, most of them very temporary and not serious, emphasising again the highly positive safety profile of these products.

Falsification

Legislation published, implementation ongoing

Falsified medicines are fake medicines that pass themselves off as real, authorised medicines. They might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose – either too high or too low. As they have not been properly evaluated to check their quality, safety and efficacy - as required by strict EU authorisation procedures - this could be detrimental to the health of citizens. Moreover, as falsifications become more sophisticated, there is an increasing risk each year that falsified medicines reach patients in the EU. They represent a serious threat to global health in general, thus requiring a comprehensive strategy both at European and pan-european level.



continued Pharma package: an update

The major threat for public health is considered by the Commission as a serious and emerging problem, which urgently needs to be tackled with a rigid legal framework. On 1 July 2011, the legislative initiative started under the Pharma package was finalised with the publication of the [new legislation on falsified medicines](#) in the Official Journal of the European Union. The new legislation will be fully applicable as of 2 January 2013.

Because of the technical complexity and the need for a rigid legal and regulatory environment, the European Commission is currently developing, via the so-called [delegated acts](#), guidance for Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) for pharmaceutical ingredients as well as guidance for the risk assessment and appropriate GMP for excipients to be published for public consultation the first half of 2012). The technical specifications of the safety features will be decided by means of delegated acts, as will the 'white' list of prescription medicines exempt from the obligation to carry a safety feature and the 'black' list of non-prescription medicines, for which a safety feature is mandatory. Criteria for this categorisation are listed in the Directive: price and sales volumes, number or frequency of past incidences of falsification, the characteristics of the medicinal product, the severity of the conditions to be treated and in general other elements contributing to a potential risk for public health. The final Directive also contains measures to regulate internet sales with the obligation to register that activity, in order to organise the control at EU and at national level.

While this new system is being put in place, the Member States will have an important role with respect to the European Commission to provide information and warning on products at risk of falsification. Together they will set up information campaigns and websites and organise and execute inspections at the premises of manufacturers and distributors of active pharmaceutical ingredients and excipients inside and outside the Community. Finally the Member States have to set up recall systems for potentially falsified measures.

Because of the differentiated approach that will become visible in the delegated acts, it is likely that homeopathic and anthroposophic medicinal products will fall outside the scope of the safety feature obligation. ECHAMP provided arguments for this to the European Commission some months ago, together with a list of the very small number of homeopathic and anthroposophic medicinal products which are prescription-only products in at least one Member State. As soon as the delegated acts consultation starts, ECHAMP will contact the European Commission in order to explain its position.

Information to patients

Still under discussion

The legislative process has been slower as regards this third part of the Pharma package. While the European Parliament was in agreement with the European Commission's proposals as regards the major topics, the Council's opinion was rather different, so no agreement has been reached on the Commission proposal.

The Commission has now finalised a revised proposal setting out clearer rules on information on prescription-only medicines and presenting a clear framework whereby companies with a marketing authorisation for a product may – and to some extent must – provide good quality and objective information on their prescription-only medicines to the general public. As a result, the proposals should lead to better empowered patients, more rational use of medicines, whilst, at the same time, maintaining the ban on advertising prescription-only medicines. As mentioned above, it also seeks to further strengthen the current system for monitoring the safety of medicines (pharmacovigilance).

The revised proposals will now go into a second reading by both the European Parliament and the Council of Ministers in line with the '[Ordinary Legislative Procedure](#)' of the new Treaty of the European Union.

Comprehensive information on the revised proposal can be found in the [press release](#) published by the European Commission on 11 October, on which day it also published the amended proposals of the



continued Pharma package: an update

Directive and the **Regulation** and an interesting **Question & Answer document**.

Since the legislative initiative will only cover information to patients on prescription-only medicines, it will only apply to very few homeopathic or anthroposophic medicinal products. And were it to apply to any of the homeopathic or anthroposophic prescription-only products, it would be difficult to make the rules consistent with the existing restrictions on homeopathic medicinal products as regards communication to patients. ECHAMP will follow the legislative process in the coming months and if needed ask for amendments in the second reading in the European Parliament.

Nand De Herdt
President of ECHAMP

European Commission programmes - the added value of complementary healthcare



© Monkey Business

A number of EU public health initiatives may offer scope to raise the profile of homeopathy and complementary medicine at EU level. The following article reports on the progress of three Commission programmes: 'Health for Growth', a new EU health programme, Horizon 2020, the future EU funding programme for research and

innovation, and the Active and Healthy Ageing Partnership. In each of these three initiatives are an opportunity and a need for the CAM community to make its voice heard.

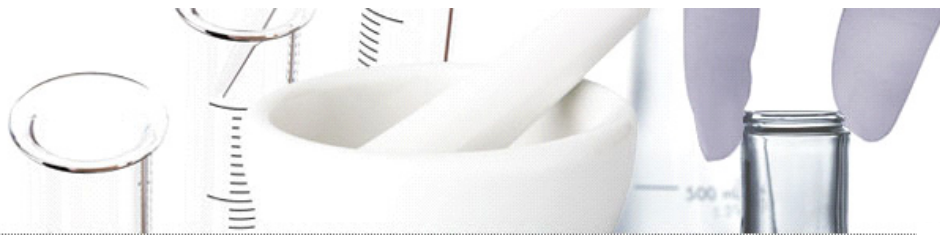
Health for Growth

On 9 November, the European Commission adopted a proposal for '**Health for Growth**', a new EU health programme, which aims to 'foster a Europe of healthy, active, informed and empowered citizens, who can contribute to economic growth'. The proposed new programme will run from 2014-2020 with a budget of €446 million and focus on concrete actions that 'offer clear EU added value'.

The Programme has the following four objectives:

- Developing innovative and sustainable health systems
- Increasing access to better and safer healthcare for citizens
- Promoting health and preventing disease
- Protecting citizens from cross-border health threats.

It will build on the activities and achievements of the two previous EU health programmes and be implemented on the basis of annual work programmes which set the priorities for project



continued European Commission programmes - the added value of complementary healthcare

funding. Calls for proposals will be issued each year, inviting stakeholders to come forward with their projects.

The proposed programme will now be discussed by the European Parliament and Council of Ministers, with a view to adoption by the end of 2013, to allow for the start of the new programme in 2014.

ECHAMP will carefully analyse the proposed programme, and develop a position statement to advocate inclusion of complementary medicine, and in particular homeopathy and anthroposophic medicine in the future initiative. While the proposal as it stands does not specifically refer to these topics, there is scope for this topic to be included in the annual work programmes.

Active and Healthy Ageing Partnership plan of action

The European Innovation Partnership on Active and Health Ageing (see [ECHAMP E-News March 2011](#)) has now published its [implementation plan](#), to include three main pillars of action, each with its own priority areas:

1. Prevention, screening and early diagnosis
 - health literacy, patient empowerment, ethics and adherence
 - personal health management
 - prevention, early diagnosis and functional decline
2. Care and cure
 - guidelines for care, workforce issues, multimorbidity, polypharmacy, frailty, collaborative care
 - multimorbidity and polypharmacy
 - capacity building and replicating successful integrated care systems
3. Independent living
 - supporting people with cognitive impairments
 - enhancing deployment and take up of interoperable independent living solutions
 - supporting social inclusion of older people.

Practical actions are being linked to priority areas in each of these topics.

This Strategic Implementation Plan is the result of six months of intensive activity and cooperation between a wide variety of stakeholders, including a Steering Group of some 30 high level representatives of industry, patients, older people, health professionals, and academics working together and various workshops involving a wider community of stakeholders.

Next steps:

It is relatively unclear what the next steps will be. The Commission has proposed setting up Action Groups to be closely involved with the implementation and monitoring of the Partnership; Council and Parliament will both respond to the Plan. However the Steering Group will be dissolved while for 4 of the 9 key priorities identified, no actions have yet been agreed.

ECHAMP responded to a consultation on the Partnership last year and is disappointed to note that the summary of submissions received did not take account of the issues we raised relating to homeopathic and anthroposophic medicinal products. Not surprisingly, the Strategic Implementation Plan does not refer to this area and its potential contribution either. It is hoped that the wider CAM community will work together to defend the legitimate wishes and concerns of the fast growing numbers of users and prescribers of complementary medicine.

Horizon 2020

Commission proposals for Horizon 2020, the future EU funding programme for research and innovation (see [ECHAMP E-News September 2011](#)) are expected to be presented by the end of November 2011, for decisions of the Council of Ministers and the European Parliament (Co-decision procedure).

It is intended that the programme will function as a more coordinated and less fragmented framework in this area, covering all research and innovation funding currently provided through a variety of different initiatives. The aim is to maximise the



continued European Commission programmes - the added value of complementary healthcare

contribution of EU funded research and innovation to sustainable growth and jobs and to tackle the main challenges facing Europe; health and the ageing of the population are amongst the key proposed research themes.

The Programme has as its three main objectives to tackle societal challenges, industrial leadership and competitive frameworks and excellence in its science base.

The first heading, tackling societal challenges, includes a work stream entitled 'Health, demographics and well-being'. It will address the following areas of research:

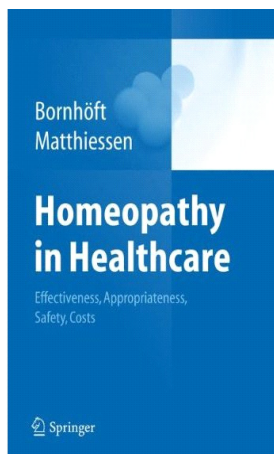
- health promotion and disease prevention, understanding the fundamentals of health and disease and ensuring empowerment for self-management of health
- curing, treating, managing disease, disability and reduced functionality
- sustainable and efficient healthcare systems.

While Horizon 2020 will only become fully operational in 2013, a [website](#) has already been launched.

When the Horizon 2020 proposal comes out, ECHAMP plans to work with its wider membership to analyse the content and prepare a response, which will include comments and suggestions on the research proposed. This can then serve as an advocacy tool with all three EU institutions as the proposal goes through the co-decision process.

Christine Marking
Public Affairs Consultant

New report in English supports effectiveness of homeopathy



A comprehensive report into the effectiveness, use, safety and cost

effectiveness of homeopathy is now available in English.

'Homeopathy in Healthcare' presents the results of the first multi-disciplinary review (Health

Technology Assessment) into homeopathy; it concludes that 'there is sufficient evidence for the ... clinical efficacy of homeopathy and for its safety and economy compared to conventional treatment.

First carried out as part of the Swiss Programme for the Evaluation of Complementary Medicine (PEK) in 2005, this report has until now only been available to the German speaking public. The unique approach of this report is its emphasis on external evidence into the effectiveness of homeopathy, as well as on more traditional types of scientific studies, such as randomised controlled trials, meta-analyses or systematic reviews.

ECHAMP hopes that the report will provide a much needed bridge for homeopathy between the world of research and the world of decision making. This new translation will make the results in favour of homeopathy more accessible to a wider range of European and national health policy makers.

Homeopathy in Healthcare - Effectiveness, Appropriateness, Safety, Costs
Gudrun Bornhöft; Peter F. Matthiessen (Eds.),
Springer 2011, ISBN 978-3-642-20637-5 €30,00
(approx)



A triumph for homeopathy in Sweden



© Alexander Rath

Even though the roots of homeopathy in Sweden date back to 1832, when Professor G Wahlenberg began to engage with homeopathy along the lines of Hahnemann, until now homeopathy has not been accepted by the Swedish health authorities as an official therapeutic approach, and doctors in Sweden have not had permission to prescribe homeopathic medicines. This is out of line with all other EU Member States, except Slovenia.

However, a recent court decision ruling the appeal by one doctor, Anders Pettersson, may change this situation, giving doctors the freedom to prescribe homeopathic remedies. This article describes his experience over the past few years.

For many years now The National Board of Health and Welfare (*Socialstyrelsen*), the Medical Responsibility Board (*Hälsa och Sjukvårdens AnsvarsNämnd*) and the courts in Sweden have penalised qualified health care professionals, including doctors and nurses for using alternative medicine, regardless of whether they were working to the same standards of professional practice as health professionals in the rest of the EU. Until 23 September this year, Sweden was the only country in the EU with the exception of Slovenia that prohibited doctors from practising homeopathy, and this on no clear grounds.

It is believed that there are to date seven doctors, one registered psychologist and one registered nurse who have been forbidden to use complementary methods of care. One doctor was forced to stop his work in Sweden, and moved to Germany to continue his practice, with the result

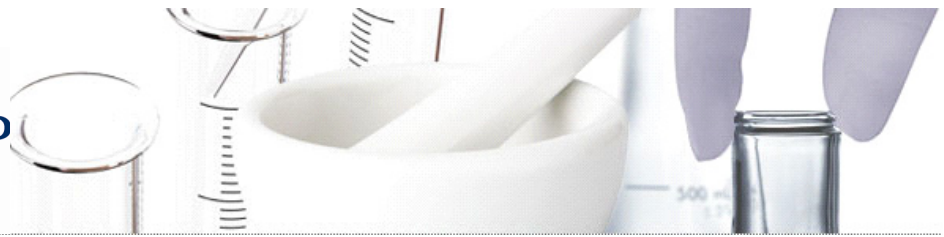
that his patients were forced to seek the medical care they wanted abroad.

The case against Dr Pettersson was started in 2003 after a lecture he gave on homeopathy, and, following sentencing in two lower courts in 2005, he was forbidden to use homeopathy. The verdict made the claim that homeopathy is unscientific, ignoring a bank of evidence submitted on his behalf and with disregard to EU legal practice.

Six years later, after years of discrimination against him and his patients, his case came at last to the highest court (formerly the *Regeringsrätten*, recently renamed the *Högsta Förvaltningsdomstolen*), this time for a fair and positive trial by the highest court. At last, on the 23 September the court decided (Dnr 6634-10) that the doctor had in no way harmed the medical safety of his patients, and that he had treated the patients quite correctly, including with orthodox medicine. Surprisingly, the court took it on itself not to make a statement about the scientific evidence for homeopathy, nor to comment on the need to apply EU legal practice.

The implications of this decision are that from now on qualified medical personnel are allowed to use complementary medicine, providing the patients want it and it is considered principally harmless. It is hoped that this decision opens the door to use homeopathy alongside conventional medicine, in Sweden now as in the rest of Europe. There is still a need to demonstrate to the Swedish authorities and courts that Sweden must follow approved international medical and legal practice.

Anders Pettersson MD



An interview with Enid Segall



*Enid Segall is President of the **European Federation of Homeopathic Patients' Associations** and Chairman of the Friends of the Royal London Hospital for Integrated Medicine. Her first contact with homeopathy was almost accidental, when on completing her education she went to work for the*

leading manufacturer of homeopathic medicines in the UK. Here she talks to Karen Chapman, editor of ECHAMP E-News, about her experience and the progress she has seen for the homeopathic patients' movement at European level.

KC How did you become involved in homeopathy?

My first contact with homeopathy came when I went to work for the leading manufacturer of homeopathic medicines in the UK. This almost accidental introduction changed my health and the direction my life was to take. The company retained the services of a homeopathic doctor and his treatment changed health patterns I thought were a part of me and that I would have for life. That personal experience combined with talking to customers and hearing accounts of their use of homeopathy convinced me of its value. It became a subject of lifelong interest and study. Later in life, working at the helm of the British Homeopathic Association, I saw the need for patient advocates.

KC What prompted the establishment of the European homeopathic patients' movement?

European law requires patient involvement, therefore when the **European Committee for Homeopathy (ECH)** was formed, one of its sub-committees was for patients and users of homeopathy. We found this a useful forum but it was felt that we needed to stand on our own in order to have more clout and so in October 2003, the **European Federation of Homeopathic Patients' Associations (EFHPA)** was

born. Since then it has grown slowly but steadily in strength and numbers.

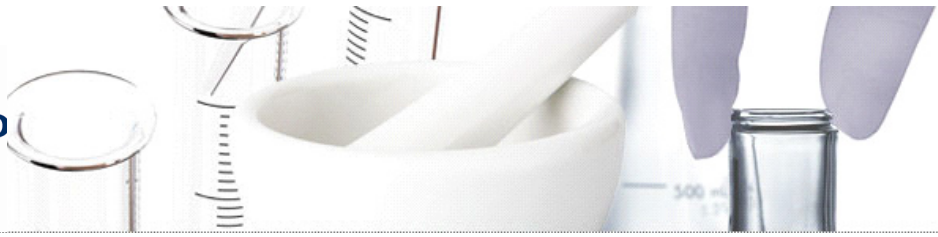
Our aim is to see a patients' group formed in every Member State. Last year we were delighted to see the formation of a group in Spain and an umbrella group of over 50 small patient groups in Germany, Hahnemannia, applied for membership. We hope that Portugal will soon follow suit and Slovenia is on the brink of forming one.

KC What progress have you seen at European level over the past five years?

While governments throughout Europe all say they put patients first, in practice this is not always obvious, which makes it even more important for patient groups to get together and lobby on their own behalf otherwise they will be completely overlooked. Although the politicians say the right things about putting patients first, it is the civil servants who put policy into operation and they are more concerned with the financial outcome of their decisions. Patient pressure is very important, not least in the EU.

At the moment the EU does not wish to deal with patients solely representing homeopathy but they are willing to think about complementary and alternative medicine (CAM) and they place homeopathy within CAM. As a result of this, EUROCAM was established, a group of representatives of different CAM therapies including homeopathy. Only homeopathy and anthroposophic medicine have patients' associations and EFHPA is regularly represented at EUROCAM meetings. Progress is being made and the group has had a meeting with Mrs Testor-Coggi, the head of DG SANCO and an active Interest Group has been formed among MEPs. Their most recent meeting highlighted research with Prof. Dr Harald Wallach as the main speaker.

EUROCAM is planning an awareness raising conference in Brussels next year which will highlight the benefits that European citizens derive from using CAM. The benefits to their health, the self-awareness that comes as a result of using homeopathic medicines and contact with a CAM therapist which in turn often lead to a change in life style. From the EU standpoint, better health and the potential cost savings for the



continued Interview with Enid Segall

health care budgets of the Member States are both major factors which we hope will convince them of the need to give priority to homeopathy and CAM in EU health policy. EFHPA believes that patients have a fundamental right to patient-centred healthcare that respects their needs, preferences and values.

Equally important is the subject of availability of homeopathic medicines. Not every country has the full range, leading to inequality of access which is not acceptable. We would like to see a better understanding of the manufacturing process leading to the full range being available throughout Europe.

How can EU research programmes support and strengthen the situation of patients in the EU?

Unfortunately homeopathy is currently being targeted to a greater or lesser degree by extremists in many European countries. Patient groups are reacting and their voice is vital to the battle to save homeopathy being turned into something only the rich can afford to choose and use.

To overcome this prejudice there must be more and better research. Only then can we face down the opposition. Recent European Parliament interest in funding research into veterinary homeopathy is a big breakthrough and one that brings hope to us all. I have long thought that the veterinary side of homeopathy is our best bet when it comes to convincing people that it is not all down to the placebo effect. More EU investment into research is essential to establish the benefits of homeopathy to EU healthcare policy in line with what patients in Europe are earnestly seeking.



Calendar 2011 & 2012

November 2011

- 30 - ECHAMP Board meeting, ECHAMP Office, Brussels

December 2011

- 1 - ECHAMP Board meeting, ECHAMP Office, Brussels
- 13 - ECHAMP PR Working Day, ECHAMP Office, Brussels

February 2012

- 9 - ECHAMP Board meeting, ECHAMP Office, Brussels

March 2012

- 8 - ECHAMP WP Public Relations, ECHAMP Office, Brussels