



ANNUAL REPORT

2010

European Coalition on Homeopathic and Anthroposophic Medicinal Products

“

2011 will reveal whether the political and regulatory will is there to work together on solutions for the benefit of the European users and prescribers of homeopathic and anthroposophic medicinal products.

Nand De Herdt, President, ECHAMP ”



Each year seems to pass more quickly and with more intense activity than the last. So it was with 2010.

ECHAMP's regulatory affairs experts have focused on pharmacopoeia, injectables, mutual recognition and safety and safe concentrations. They have drafted policy documents, which in some cases have already been discussed with decision makers, and have started to address Article 16.2 marketing authorisations.

The pharmapolitical affairs working party has focused on the complex regulatory situation for certain categories of the medicinal products and on the 'regulatory deficit' in a number of EU Member States. The crucial question will be to find an appropriate regulatory environment for all the medicinal products that belong to the two European and specific therapeutic systems homeopathy and anthroposophic medicine – one that ensures both that the products meet sufficient quality, safety and effectiveness requirements and that they can all remain available for the therapeutic system. Notably, last year's World Health Organisation (WHO) report, 'Safety issues in the preparation of homeo-

pathic medicines', explicitly recognises a number of well-established variations to the original ideas of Hahnemann.

In the field of legislation, the so-called Pharma Package was high on the Brussels agenda. The new legal provisions for limiting the risk of falsification will oblige manufacturers to put a safety feature on the packaging of prescription only medicines, with the exception of those on a 'white list'. Non prescription medicines will be exempt from the obligation, except those on a 'black list'. Proposals for list entries of medicinal products or product categories will be done by the European Commission. As regards the new legislation on pharmacovigilance, those homeopathic medicinal products which have been granted a national marketing authorisation in accordance with Article 16.2 will be subject to a regular Periodic Safety Update Reports (PSUR) declaration. This will present a good opportunity to provide once again proof of the positive safety profile of these medicinal products.

During the year, ECHAMP's good contacts with the Spanish and then the Belgian EU Presidency, and later on with the European Commission and the Homeopathic Medicinal Products Working Group (HMPWG) of the Heads of Medicines Agencies (HMA), have opened new perspectives for our regulatory concerns. As a result of these discussions, a regulatory status report on homeopathic

and anthroposophic medicinal products in the EU Member States has been commissioned, and this will be followed by a regulatory impact assessment report in the second half of 2011.

The broader context provides greater support for complementary medicine in Europe: the start-up of the CAMbrella project, the founding of European Information Centre on Complementary and Alternative Medicine (EICCAM) and of European Scientific Coalition on Anthroposophic Medicinal Products (ESCAMP), and the welcome creation of an interest group on CAM by a number of MEPs.

From an internal perspective, but no less important, ECHAMP has experienced a complete change of office staff this year. For different personal reasons, each of our three full-time employees decided to leave. We are very pleased to have filled all the positions - executive manager, public relations and events officer and office assistant, and now have a strong new team established and ready for the challenges ahead.

You will find further details on these and all our activities in this annual report. We look to an intensive year with many new opportunities. 2011 will reveal whether the political and regulatory will is there to work together on solutions for the benefit of the European users and prescribers of homeopathic and anthroposophic medicinal products. ■

Pharmapolitical affairs

In 2009, this working party mapped out the problems faced by the industry. During 2010 it worked towards a proposal for a legal and regulatory framework that is appropriate for these medicinal products, issued as they are from specific therapeutic systems. A programme of expert activities is in place, including studies and publications, to generate the justification and the technical and scientific basis for this new regulatory approach.

Pharmaregulatory affairs

■ Subject group:

Pharmacopoeia monographs

This group deals with all topics related to the quality of raw materials and substances. In 2010 it submitted comments to the European Directorate for the Quality of Medicines & HealthCare (EDQM) on the European Pharmacopoeia (Ph. Eur.) draft monographs 'Homoeopathic pillules' and 'Pillules for homoeopathic preparations' published in Pharmeuropa.

■ Subject group:

Pharmacopoeia policy

Establishing scientifically meaningful, feasible and harmonised quality criteria for homoeopathic preparations in the Ph.Eur. is still a major challenge. ECHAMP member companies are further developing their position, writing

ECHAMP Board of Management

Back row from left to right:
Bernadette Krom-Mc Donagh,

Dr Gunther Herr,

Giovanni Gorga,

Dr Gesine Klein,

Dr Barbara Sterner,

Dr Werner Driehsen

and Max Daege.

Front row from left to right:

Christiaan Mol,

Nand De Herdt

and Per Engström,

Executive Manager





position papers to the EDQM and the EU Commission as needed. A number of experts, including academics, are developing ideas through an ad hoc discussion group.

■ **Ad hoc initiative on the safety of injectables**

This group aims to help the political acceptance of homeopathic injections, for which applications for marketing authorisations continue to be denied. Amongst other planned initiatives, an evaluation of the pharmacovigilance databases of the ECHAMP companies is almost complete, in follow up to the enquiry on the 'Safety of homeopathic injectables for subcutaneous administration' published in 'The Journal of Alternative and Complementary Medicine'.

■ **Subject group: Safe concentration list**

In 2010, the HMPWG finalised the forms and documents needed to start the process for determination of a common European list of First Safe Dilutions (FSDs) for single remedies. It is still unclear as to whether the HMPWG will do the assessments and define the FSDs itself. The subject

group is ready to comment when they are published.

■ **Subject group: Mutual recognition/decentralised procedure (MRP/DcP)**

There is still very little experience of mutual recognition or decentralised procedures for homeopathic medicinal products. A perceived disproportion between effort and benefit broadly prevents our industry from making use of these procedures. This subject group did not meet in 2010.

■ **Subject group: Regulatory affairs**

This group mainly comments on draft documents in the field of regulatory affairs for homeopathic or anthroposophic medicinal products where these are not covered by other expert groups of ECHAMP. 2010 provided no direct task for this group.

Development and support for Eastern European countries

Little progress has been made in the renewed attempt to achieve a closer co-operation between ECHAMP



Manufacturing in accordance with Good Manufacturing Practice

partner companies in Poland, predominantly because of the negative outcome of the updating procedure. Products and whole lines of ampoules have had to be taken off the Polish market, with some members considering withdrawal from the market altogether. The working party goal is to strengthen our presence in the branch association Farmacia Polska so as to avoid a further fiasco in the upcoming renewal procedure.

In Lithuania, the 2008 ECHAMP initiative achieved unexpected success with the implementation of Article 16.2 of the European Directive in early 2010. The draft proposals had been intensively commented on by members, who had also visited the authorities during the final phase

of the implementation procedure. A research project was initiated for collecting relevant data in individual CEEC countries.

Public relations

The PR working party continues to support the communication activities of the association through the regular ECHAMP E-news, an up-to-date and enhanced website, media communication and the organisation of special events, such as the expert workshop in Madrid, and support for the 3rd EU Homeopathy Day in the European Parliament. In 2010 it has taken a particular initiative to improve internal communication with the ECHAMP members. ■

The most relevant question for the coming year is how to develop a regulatory environment which is fit for purpose.

Regulatory affairs status in 2010

There was little external input into the regulatory affairs work in 2010 and the situation remains almost unchanged compared to 2009. We are still afraid that regulatory requirements will be implemented without further discussion, despite serious doubts based on valuable arguments. Although it is a major pre-condition for the quality of homeopathic and anthroposophic therapy in the EU to maintain a diverse range of specific medicinal products, we believe this diversity to be endangered by disproportionate requirements, without any additional contribution to quality or safety.

Nevertheless, this calm has allowed for more intense reflection and internal

discussion about the regulatory challenges in the EU and really meaningful regulatory criteria. Quality, safety and effectiveness are beyond discussion for the ECHAMP member companies. However, integration into the regulatory concepts of the characteristics of the medicinal products of the specific therapeutic approaches of homeopathy and anthroposophic medicine – and here the reference to the therapeutic approaches as well as to the pharmaceutical tradition of the medicinal products is explicit – will be mandatory in order to sustain the range of products needed by patients and practitioners within the EU.

In addition, we are increasingly aware of the structural problems relating to different definitions of our applications and dossiers in the various Member States. This represents a major threat to the efficient use of multi-state registration procedures as well as to efficient maintenance of existing registered dossiers.

On 8 December, HMPWG invited the industry to a hearing in Liège in Belgium. ECHAMP took part with a delegation of nine experts from

five Member States. The chair and vice-chair of this hearing referred to the joint responsibility of competent authorities and industry for the supply of users with good quality medicinal products of their choice as well as to the need for adequate evaluation criteria. The broad attendance of the meeting was interpreted as a sign of the commitment on both sides. ECHAMP was invited to present our vision on the regulatory process up to 2025 as well as some current challenges and concerns. We addressed the need for action regarding some

existing Points to Consider documents, showed some practical calculations with respect to the First Safe Dilutions, presented our experiences with MRP/ DcP and referred to the structural problems of existing applications and dossiers. We offered our co-operation and asked for direct exchange at expert level in order to support further progress in our field.

The most relevant question for the coming year is how to develop a regulatory environment which is fit for purpose. ■

Quality checks of raw materials and good documentation of the manufacturing processes



The current system poses severe threats to the affordability and availability of and access to our products, as well as to the future of our businesses.

CEOs meet Health Commissioner John Dalli

In October, chief executives of some ECHAMP member companies met Health Commissioner John Dalli and members of his staff, Nils Behrndt and Maria A. Figuerola Santos, with the aim of raising the Commissioner's awareness of the impact of the current EU pharmaceutical legislation on the homeopathic and anthroposophic medicinal industry, and to explain the main shortcomings of this legislation including the regulatory environment.

The group sought to make the case for appropriate pharmaceutical legislation which takes account of the specific characteristics of these products, and to win the Commissioner's support for a future review of the current legislation, positioning ECHAMP as a partner and

expert in the process. They underlined the widespread use of the products, the benefits for patients and issues in relation to safety, affordability and choice. The current system poses severe threats to the affordability and availability of and access to our products, as well as to the future of our businesses.

Mr Dalli expressed his interest in the issues and advised ECHAMP to investigate the reasons for the lack of progress in relation to registration and authorisation. He outlined a step-wise approach: first to consider infrastructural measures, then to address regulatory measures and – if these do not lead to solutions – to review the existing legislation. He proposed an expert workshop during 2011, with political and regulatory decision makers in order to debate the situation and make progress towards possible solutions.

The discussion contributed to a better mutual understanding and awareness and set a good precedent for future co-operation.

Public health

In 2010 relevant Commission activities

in public health included the new EU Research & Development Framework Programme, and a consultation on the future review of the veterinary pharmaceuticals Directive. In its report, the Commission identifies the restrictions and the unnecessary burden this complex legislation places on the veterinary pharmaceutical industry. In its response, ECHAMP argued that these arguments could equally well be applied to the legislation for homeopathic medicinal products and thus that this may set a welcome precedent for a detailed review of the legislation on pharmaceutical medicinal products for human use.

Belgian EU Presidency

In March, Belgian Health Minister Laurette Onkelinx expressed her commitment to progress an initiative regarding EU legislation in relation to homeopathic and anthroposophic medicinal products during the Belgian Presidency. This support led to two concrete initiatives for action during 2010 - a survey on the EU regulatory situation of homeopathic and anthroposophic medicinal products,

and a meeting with the HMPWG with external experts in these products.

The survey was planned to be deliberately impartial and objective, and thus, after careful review of a number of proposals, was carried out by PricewaterhouseCoopers. The preliminary outcome was fed into the HMPWG meeting in early December. The draft document already provides a picture of the unclear and unharmonised regulatory situation of these medicinal products in Europe.

European Parliament Resolution

As a result of ECHAMP's 2009 contact programme with Members of the European Parliament, Daciana Sarbu MEP (R-S&D) tabled a Motion for a Parliament Resolution on establishing a harmonised framework for homeopathic products. The Resolution calls on the Commission to 'modify the existing pharmaceuticals Directive .. so as to ensure the free movement of homeopathic products and take proper account of their specific nature'. ■

100 millones de europeos confían su salud a la Homeopatía

Building a common platform in the EU

In April, ECHAMP's expert seminar in Madrid brought together a panel of speakers to present and discuss new initiatives by key stakeholders in the complementary medicine sector to speak with a united voice at EU level. The aim was to build further collaboration in order to secure the future of homeopathic and anthroposophic medicinal products at EU level.

The panel of speakers included Nand De Herdt from ECHAMP and representatives of the leading European associations and new alliances in the sector: CAMDOC alliance, which represents medical doctors practising complementary medicine, European Federation of Complementary and Alternative Medicine (EFCAM),

the European Federation of Homeopathic Patients' Associations (EFHPA), European Federation of Patients' Associations for Anthroposophic Medicine (EFPAM), the alliance around the EU Homeopathy Day, and the CAM Stakeholder Group.

Together the speakers presented a comprehensive picture of the many new initiatives that are underway to raise awareness on the importance of complementary and alternative medicine in the EU; this is reflected in increasing visibility of the issues

in the EU institutions, and there are signs that the European Commission is more open to considering CAM. Nevertheless there remains an obvious mismatch between the needs and demands of the 100 million patients of homeopathy and anthroposophic medicine and the lack of priority given to these therapies and their medicinal products at EU level.

The seminar was attended by ECHAMP's full, corresponding and associated members, as well as by many interested experts from Spain.

Madrid Press Conference

'100 millones de europeos confían su salud a la Homeopatía' was the title of the press conference organised by ECHAMP and Spanish member DHU Ibérica, in Madrid in April. ECHAMP's presence attracted a great deal of interest in the Spanish media, generating over 50 articles in the national press. The reporting covered the story from a Spanish angle, showing the deficit of appropriate legislation in Spain, and the difficulties that it can bring to the sector. ■



Madrid press conference from left to right: Dr Miguel Martínez-Falero del Pozo (NAMA), Nand De Herdt (ECHAMP), Enid Segall (EFHPA) and Alex Castilla (DHU Ibérica)



Madrid expert seminar 'Building a common platform in the EU'

“It is time to act to ensure that EU health policy fully reflects the needs and choices of its 100 million patients of homeopathy.”

European Parliament Interest Group on CAM

Some 35 MEPs have expressed their support for the new European Parliament Interest Group on Complementary and Alternative Medicine (CAM), which aims to put and keep the topic on the EU policy agenda, providing a forum for discussion and action, and promoting awareness of the value of a more holistic approach to health.

The MEPs acting as co-chairs are Marian Harkin (IRL-Independent), Elena Oana Antonescu (R-EPP), Liisa Jaakonsaari (SF-S&D), Sirpa Pietikäinen (SF-EPP), Thomas Ulmer (D-EPP) and Giles Chichester (UK-Con). Constituent and co-chair meetings were held during 2010, to discuss the aims, governance structure, work programme and dates for future meetings.

The first full meeting was held in November, addressing availability of complementary medicine products. Nils Behrndt (Cabinet of Health Commissioner John Dalli) was one of the speakers as was Nand De Herdt, President of ECHAMP. The meeting was attended by 4 MEPs and 16 assistants, as well as by outside stakeholders. The next meeting in spring 2011 will address the role of CAM in healthy ageing and long term care.

This is an initiative of the CAM Stakeholder Group. The secretariat is provided by the European Committee for Homeopathy (ECH).

3rd EU Homeopathy Day

The 3rd EU Homeopathy Day on 23 March in the European Parliament was opened by host Marian Harkin MEP with a call to action: “The European Parliament and the European Commission are already working to develop health policies that reflect the needs, requirements and preferences of the patients of Europe. It is time to act to ensure that EU health policy also fully reflects the needs and choices of its



3rd EU Homeopathy Day
– Marian Harkin MEP
and Stephen Gordon,
ECCH

100 million patients of homeopathy.”

The event focused on patients’ choices, emphasising the benefits of integrating homeopathic and anthroposophic treatment into mainstream health care, and highlighting the fact that the millions of Europeans who choose these treatments need much improved access to affordable health care services across Europe and wider availability of the full range of products for these therapies. Chair Stephen Gordon, General Secretary of European Central Council of Homeopaths (ECCH), explained

how demands from the patients of homeopathy are in line with EU health policy, which focuses on patient empowerment and on patient-centred and individualised treatment. However despite the vast number of users of these therapies in Europe, there is no real priority given to homeopathy or complementary medicine in EU health policy or programmes.

EU Homeopathy Day is a joint initiative of the European associations of patients, doctors, practitioners, pharmacists and industry in the field of complementary medicine in Europe. ■

Visit www.echamp.eu for further information about ECHAMP and its activities.



Membership Assembly 2010

The 2010 ECHAMP Membership Assembly was held in Madrid in April, chaired by Max Daege, former president of ECHAMP. Members were invited to visit the Homeopathic Hospital San José, the first Spanish homeopathic hospital, which was founded in 1878. The 2011 Membership Assembly will take place in Warsaw on 10 May, in line with the Polish Presidency of the EU in the second half of 2011. Max Daege will again chair this event.



ECHAMP Membership Assembly, Madrid 2010

The Association

ECHAMP now has 54 full members from 18 Member States, as well as 14 corresponding and 10 associated

members. Some members left at the end of 2010, mainly because of the switch in their main business from homeopathic to herbal medicines or food supplements. We are very pleased that a number of other companies have applied for membership and will join in 2011.

Publications

ECHAMP provides extensive information on homeopathic and anthroposophic medicinal products in Europe through its website, brochures, reports, and the regular ECHAMP E-news. The ECHAMP website homepage is considered a solid source of information for legal and regulatory information on these products in Europe.

The ECHAMP office has seen some changes to its staff in 2010, and three new employees have joined the team: Per Engström, executive manager, Melanie Vritschan, PR and events officer and Amandine Oset, office assistant.

Please visit www.echamp.eu to subscribe to the newsletter or download the ECHAMP booklets. ■

ECHAMP office team

From left to right: Sônia Costa, Amandine Oset, Melanie Vritschan, Ana Laura Blanco Gutiérrez, Per Engström and Magdalena Jasinska.

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ECHAMP is the European Coalition on Homeopathic and Anthroposophic Medicinal Products. It represents the vast majority of the industry for these products in Europe. Homeopathy and anthroposophic medicine should be fully integrated into health care provision in Europe.

ECHAMP works towards an appropriate European legal and regulatory framework to ensure the easy availability of the full range of these medicinal products, essential for the successful practice and development of these traditional therapies.