ECHAMP

ANNUAL REPORT 2012

European Coalition on Homeopathic and Anthroposophic Medicinal Products

“When will the politicians find the courage to respond to the significant demand from Europe’s citizens with legislation that makes these medicinal products available and affordable across the EU?”

Nand De Herdt, President, ECHAMP, January 2013

PRESIDENT'S STATEMENT

New figures show highly significant demand for CAM and its medicinal products

There were some important developments for complementary and alternative medicine (CAM) in 2012: new figures showed highly significant demand for CAM and the related medicinal products, and there were signs of further integration of CAM in the health policy of certain Member States and regions, health care providers and institutions. Some high profile European CAM events enabled open discussions with decision makers and politicians.

Many of them say to us: I use CAM for my family and for my children.

So what are they waiting for? How long will the authorities consider complementary medicine as only a third or fourth option for daily health while increasing numbers of citizens use it as a first or second choice?

At the start of the current legislative term of the European Commission and the European Parliament in 2009, it became clear that these institutions did not prioritise improvements to the legislation for homeopathic and anthroposophic medicinal products. The political and regulatory authorities advised us, quite rightly, to keep trying to make the current legal and regulatory environment work more effectively.

The legal basis for homeopathic medicinal products has now been in place for twenty years – half the professionally active time of a human being. The outcome of this legislation, both in terms of enforcement and as regards harmonisation, can only be described as disappointing for all the stakeholders concerned: patients, prescribers and industry, not forgetting the competent authorities themselves, the vast majority of whom suffer from insufficient capacity to do the work.

As austerity measures are being taken across the EU, the economic challenges it faces should alone be sufficient incentive to make more efficient use of the budgets for health and medicinal products.

The EU's own efforts in the field of research indicate that the time is right to investigate the added value in terms of quality, safety, effectiveness, cost-effectiveness and sustainability that complementary medicine, including homeopathic and anthroposophic medicinal products, can offer for the health and well-being of the citizens of Europe.

The big question remains: how can the nice words and principles – free circulation, free choice of therapy, availability and affordability of CAM health care services and products, harmonisation, simplification, better regulation, smart regulation, proportionality – be turned into daily reality for citizens and businesses?

Governments and decision makers at both EU- and national level would do better to allocate budgets to research in complementary medicine than to spend large amounts on administrative and regulatory work that neither adds value to the quality or safety of the products, nor contributes to the original aim of the pharmaceutical legislation, which is to safeguard public health.

The legislative term of the European Parliament and the European Commission comes to an end in 2014. When will individuals within these legislative institutions find the political courage to start an initiative to finally regulate this field appropriately and create legislation that will make homeopathic and anthroposophic medicinal products available to and affordable for all citizens of Europe? Such an initiative can only be in the interest of the citizens, the industry that wants to grow and invest and the European Union that otherwise makes so much effort for the health of its citizens.

ECHAMP will defend its positions with more energy than ever before, with particular emphasis on the quality and safety of the medicinal products its members produce for self-medication and for medical treatment by practitioners, and on their effectiveness within the framework of their therapeutic systems of origin, homeopathy and anthroposophic medicine. ■

POLITICAL ACTIVITY

A recent review shows that the overall regulatory framework for these medicinal products is not fit for purpose

ECHAMP's political activity in 2012 was intensive, also providing a platform to communicate its main objective of maximum availability of homeopathic and anthroposophic medicinal products for patients and practitioners across the EU.

ECHAMP's main objective is maximum availability of these medicinal products.

Pharmapolitical activities

ECHAMP participated in consultations and meetings of relevance to our medicinal products, in particular concerning the topics pharmacovigilance and falsification. We had one face to face meeting with Commission staff members in charge of making the proposals, where we discussed our specific concerns and explained the particular characteristics of homeopathic and anthroposophic medicinal products, their excellent safety profile, the large number of products, the low turnover per product and the size of the companies.

In addition, ECHAMP continued its work on proposals and the justification for a harmonised EU-wide legal and regulatory approach to homeopathic and anthroposophic medicinal products with indications (mostly used for self-medication) and to injectables (prescribed by medical professionals). Final documents and publications are now ready to defend ECHAMP's positions as regards future proposals for an EU-wide solution of specific rules for the proof of safety and effectiveness for Article 16.2 marketing authorisations. As concerns injectables, we are helped by the publication in June 2012 of the results of a new safety study on homeopathic and anthroposophic injectables in the scientific journal *Pharmacoepidemiology & Drug Safety: 'Adverse drug reactions to anthroposophic and homeopathic solutions for injection: a systematic evaluation of German pharmacovigilance databases'* by Miek Jong, Mats Jong and Erik Baars.

Availability

Availability, or lack of EU-wide availability, of medicinal products for human use in the EU is a key topic for the European Commission and other political and regulatory bodies. It is likely to surface again in 2013 when the Commission will make public the findings of a study on this topic. One of the objectives of the study, which includes reference to homeopathic and anthroposophic medicinal products, is to identify how the current regulatory framework can be used to alleviate issues with availability. It is hoped this will lead to solutions and, if needed, regulatory or legal initiatives.

ECHAMP's own report on the availability of homeopathic and anthroposophic medicinal products in the EU was finalised in 2012, including two surveys by PwC, one on the progress as regards registrations, marketing authorisations and finalised mutual recognition procedures of these products, and the other on the availability of these medicinal products for patients asking for them in pharmacies. The full report will be considered as part of the Commission's own study.

Public health

ECHAMP also addressed the following initiatives in the broader field of public health:

Horizon 2020: The first proposals for Horizon 2020, the EU funding programme for research and innovation (2014 to 2020) have been going through the European Parliament and Council of Ministers.

ECHAMP has formulated amendments to the programme proposals, suggesting the need to strengthen references to better and integrated health care, respecting freedom of choice for patients, patient-centred healthcare and optimising the delivery and choice of health care to European citizens by identifying successful interventions, including complementary and alternative medicine.

ECHAMP's proposed amendments are in line with the current EU health agenda which emphasizes patient-centredness (informed patients taking responsibility for their health and treatment options) and integration and partnerships (better cooperation between the various disciplines and stakeholders).

On 28 November, the European Parliament's Committee on Industry, Research and Energy (ITRE) considered amendments tabled by German Christian-Democrat MEP **Angelika Niebler**, adopting a statement to the effect that research into interventions of complementary and alternative medicine should be included in the programme in efforts to maintain effective health and care for all ages.

The report will be voted in the Plenary in the first half of 2013 and will then need to be accepted by the Council of Ministers.

Chronic disease: In April, ECHAMP responded to a European Commission discussion document on the priorities for action in the field of chronic disease. ECHAMP highlighted the important contribution of homeopathy and anthroposophic medicine in relation to patient choice and self-management of health.

ECHAMP's response also reiterated the need for healthcare systems to be based on the principle of 'integrated healthcare'. It presented the positive benefits, both in terms of patient safety and in terms of better health outcomes and sustainable health budgets, of finding alternatives to the strong prescription medicines often prescribed to treat chronic disease, with their sometimes severe side effects. ECHAMP also recommended priority areas for research into homeopathy and anthroposophic medicine.

Legal environment

Smart regulation: In July, ECHAMP responded to a European Commission consultation on 'Smart Regulation', the initiative which aims to ensure that EU legislation is effective without being overly burdensome. ECHAMP members face a number of problems in relation to the current legal framework, which obliges industry to apply for market access authorisation for the same products in each of the individual 27 Member States, resulting in huge costs to put and keep products on the EU market. Furthermore, the practical implementation of the Mutual Recognition Procedure requires disproportionate work.

In its response, ECHAMP welcomed the Commission's intention to introduce so-called 'fitness checks' to assess whether the regulatory framework for a specific policy area is fit for purpose; a recent review clearly shows that the overall regulatory framework for homeopathic and anthroposophic products is inadequate, and that the enforcement of the legislation in this area is far from complete - twenty years after publication.

There is a new study on the safety of homeopathic and anthroposophic injectables.

Small- and medium-sized enterprises: ECHAMP also participated in the Commission consultation on the 'Top 10 most burdensome legislative acts for SMEs'. As we did for 'Smart regulation', we stressed that the regulatory environment as created by Directive 2001/83/EC and its Annex Directive 2003/63/EC has led to major problems for all the stakeholders in the field of homeopathic and anthroposophic medicinal products.

ECHAMP's responses to the Commission's consultations can be found on the ECHAMP website. ■

REGULATORY ENVIRONMENT

How can we make our voice heard and taken seriously, especially during European regulatory affairs consultations?

For a number of years, ECHAMP has battled with the challenge as to how to make heard the specific needs of homeopathic and anthroposophic medicinal products for an appropriate regulatory environment. 2012 was no exception.

Implementation of the Pharma Package

Major developments in 2012 on two topics of the Pharma Package, falsification and pharmacovigilance, have led to some confusion as regards the situation for homeopathic medicinal products, both for applicants and for a large number of national competent authorities. There are a number of rules for which, for practical reasons, the laws can hardly be applied to these products. Competent authorities give different or conflicting interpretation on the same legal provisions. The Commission is aware of some of these difficulties, and has come up with some clarifications. However, the consequences in terms of the additional administrative burden and costs of the new pieces of legislation will become clear only after implementation in the Member States followed by the enforcement of the new rules down to the last details.

EMA fees

The issue with the biggest potential for negative economic impact on our business sector in 2012 was the concept paper launched by the European Commission on the fees for new pharmacovigilance activities, for which the European Medicines Agency (EMA) became responsible with the implementation and enforcement of the new pharmacovigilance legislation.

There are two issues of particular relevance to our industry: firstly the fees to be charged for Periodic Safety Update Reports (PSURs), because, according to Directive 2001/83/EC revised by Directive 2010/84/EU, the obligation to submit PSURs will continue for homeopathic medicinal products authorised according to Article 16.2 of the Directive. This is relevant in those countries where Article 16.2 authorisations are not regulated under the category of medicinal products with well-established use. Secondly the annual fee for products in the Eudravigilance database (EVDP): the Commission has proposed €80,000 for a PSUR for products older than two years and an annual fee of €1,000, without further differentiation of categories of medicinal products.

In ECHAMP's response, it asked for reconsideration of the proportionality principle: to factor fees in relation to the actual work carried out by EMA (for the PSUR) and to the actual service provided to companies (for the annual service fee).

With respect to the PSURs, ECHAMP requested a dramatic decrease in the fees for well-known products such as homeopathic medicinal products, proposing as a principle for calculation that the number of serious ADRs per report period be used as a measure for the assessment efforts, or that existing national fees be used as a benchmark for almost purely national non-centrally authorised medicinal products, respecting the existing diversity of national medicinal products in the EU. ECHAMP also proposed decreasing fee levels for products which have been on the market for a longer period of time (for example longer than 10 years). Regarding the annual service fee for the EVDP database, ECHAMP presented the position that fees should be charged only to the beneficiaries of EMA services. In addition, it pointed out that the database to which information on medicinal products under article 57(2) of the Regulation 1235/2010 is submitted should be paid for by public funding, as this is a sovereign task.

Since the concept paper as launched by the European Commission has been severely criticized by a large number of stakeholders, some changes can be expected.

Variations

ECHAMP responded to the European Commission's consultation on the review of the variation guidelines in summer 2012. It proposed some details specifically for homeopathic

medicinal products, identifying and justifying opportunities to decrease the administrative burden.

First safe dilution

In summer 2012 the Homeopathic Medicinal Products Working Group of the Heads of Medicines Agencies (HMPWG of the HMA) published, for the first time, assessment and list entry reports for 14 substances. They include first safe dilutions for all age and patient groups, as well as first safe dilutions with restrictions in use for specific patient groups. ECHAMP's First Safe Dilution Subject Group gave detailed comments on the proposals at the end of November. As perceived so far, the proposals from the HMPWG are based on the 'Points to consider on non-clinical safety of homeopathic medicinal products of botanical, mineral and chemical origin'; the dilutions that will appear in the list are seen as absolutely safe so it is expected that no additional data will be asked for in the registration process for those substances.

At the end of 2012, the Committee on Herbal Medicinal Products (HMPC) at EMA published a statement for consultation on the use of herbal medicinal products containing toxic and possibly carcinogenic unsaturated pyrrolizidine alkaloids (PAs). As the recommendations of this concept paper are likely to be applied to both herbal and homeopathic medicinal products, ECHAMP will also contribute to this discussion.

Outlook for 2013

The need for a regulatory environment that is appropriate to the specific needs of homeopathic and anthroposophic medicinal products is now more urgent than ever before.

Going forward into 2013, we are faced with two significant questions:

- How can we achieve adequate follow-up in the frame of legal conditions which are often difficult to understand?
- How can we make our voice heard and taken seriously during European consultations?

On the one hand, the legal situation of homeopathic medicinal products is quite unique and not enforced in an ideal way. The new provisions for pharmacovigilance provide a good example: firstly, Directive 2001/83/EC as amended, the highest level of regulation, foresees in title IX pharmacovigilance provisions for simplified registrations of homeopathic medicinal products according to Articles 14 and 15. This is in contradiction to the provisions of Article 16.3 (corresponding to title III of the Directive), which excludes this type of product completely from the provisions of title IX. Secondly, nearly all marketing authorisations of well-known products were provided with the waiver for the obligation to submit a PSUR – including generic products, those with well-established use and herbal medicinal products. Only homeopathic marketing authorisations, which have probably the highest safety profile of all of these products, were excluded from this waiver.

On the other hand, experience shows that it is quite difficult to find anyone to listen to our small voice asking for highly specific needs within the overall discussion. A great deal of expertise and practical industrial experience in the field of production of these medicinal products is required to understand and to regulate them appropriately. The industry remains open to demonstrate to the policy makers the manufacturing processes in situ.

The need for a regulatory environment that is appropriate to the specific needs of homeopathic and anthroposophic medicinal products is now more urgent that ever before.

The Commission's concept paper on EMA fees, with its very specific relevance to homeopathic medicinal products, has in fact, the potential to kill this industry. This is no longer just an administrative question but a serious political topic. ■

Homeopathic medicinal products continue to be accepted and integrated in the European Pharmacopoeia

Quality is of utmost importance to ECHAMP, so we are very pleased by the notable progress on the acceptance and integration of homeopathic medicinal products into the European Pharmacopoeia, the single reference work for the quality control of medicines for its signatory states, including the EU Member States, as managed by the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe. ECHAMP has been able to contribute to this work, drawing on the expertise of its members.

The integration of standards for homeopathic and anthroposophic preparations in the European Pharmacopoeia continued in 2012. The homeopathic manufacturing methods HAB 17 (the so called LM potencies) and HAB 39 (sugar coated homeopathic pillules) as well as the quality control monographs of Atropa belladonna, Strychnos nux-vomica and Strychnos ignatii for homeopathic preparations, were commented after publication in *Pharmeuropa*, the EDQM publication that provides updates on the European Pharmacopoeia. The general monographs on 'foreign matter', 'mother tinctures for homeopathic preparations' and the umbrella monograph 'homeopathic preparations' were also commented. ECHAMP would be very pleased to see its qualified input implemented in the new and revised monographs in the European Pharmacopoeia.

The issue of mandatory assays for non toxic preparations is still under debate. However the contrasting positions, 'for' and 'against' assays are starting to enter into dialogue. This is reflected in the 'Technical Guide' for the compilation of monographs, in which assays will be required 'if necessary'. It is no longer a general mandatory requirement. The discussion needs to be continued and substantiated with arguments. A delegation of ECHAMP is contributing to a scientific article on this and other quality control issues. ■

ECHAMP's members contribute to work on the European Pharmacopoeia.

'There is a need to establish scientific knowledge that enables citizens, health care providers, policy makers and researchers to make informed decisions about CAM' (CAMbrella)

A number of initiatives this year have helped raise awareness amongst European policy and decision makers of the important contribution CAM makes and can make in European health care.

CAM Interest Group addresses cancer

The 'MEPs for CAM' Interest Group, formed in 2010, is an informal group of Members of the European Parliament with a special interest in CAM.

In 2012, the group organised a joint meeting with the 'MEPs against Cancer' Interest Group on the contribution of CAM in the treatment of cancer. Surveys have shown that more than a third of cancer patients in Europe use CAM to increase their body's ability to overcome the disease, help deal with the side effects of conventional treatment, and alleviate physical and/or psychological distress.

Speakers included Prof Dr Harald Matthes (Community Hospital Havelhöhe, Berlin), Prof Dr Gustav Dobos (University Duisburg-Essen), Mrs Hedi Broson (Norwegian Cancer Society) and **Alojz Peterle** MEP (EPP – Slovenia), who reported on his personal experience and decision to opt for complementary medicine approaches to successfully overcome his own cancer.

Participants discussed the need for good information about the various treatment approaches in conventional medicine and CAM, including information on the benefits and limitations of both approaches.

Innovation and added value for European healthcare

A landmark conference on CAM was held at the European Parliament in Brussels on 9 October 2012, organised by EUROCAM, the stakeholder group of European umbrella organisations of patients, physicians and practitioners working in CAM, and part-funded by the European Commission.

The event was hosted by **Elena Oana Antonescu** MEP (EPP, Romania) and co-hosted by MEPs **Sirpa Pietikäinen** (EPP, Finland) and **Alojz Peterle** (EPP, Slovenia).

The conference discussed the potential that CAM has to maintain health, prevent ill-health, promote healthier lifestyles and contribute to the sustainability of health systems, stressing how CAM can fit into the EU Health for Growth Programme and the economic and innovation priorities of the EU.

CAMbrella Roadmap for CAM research

CAMbrella, the pan-European research network for CAM, presented the findings of its three year work programme at a final conference in Brussels on 29 November. CAMbrella was established under the European Commision's Seventh Framework Programme (FP7) in January 2010.

The project's results included the Roadmap for European CAM research. CAMbrella's vision is for a robust picture of CAM use and reliable information about its cost, safety and effectiveness in real world settings. The Roadmap stresses the need to establish scientific knowledge that enables all the stakeholders including citizens, healthcare providers, policy makers and researchers to make informed decisions about CAM. It identifies priorities for future European research, including focus on the prevalence of use of core CAM treatment disciplines, citizens' access to and preferences for CAM provision, identifying the most promising CAM treatment options for the most prevalent health conditions, with a clear emphasis on evaluation of CAM as an additional or alternative treatment strategy, the economic effects of CAM in European healthcare, CAM safety issues and different models of CAM healthcare integration into routine care programmes.

It also recommended the establishment of a European research centre for CAM, to collect and disseminate valuable CAM research findings for European citizens, CAM providers and the scientific community. ■

Visit www.echamp.eu for the latest news and background information on this sector

Membership Assembly 2012

ECHAMP's annual Membership Assembly took place in Copenhagen on 23 and 24 April. The first day was dedicated to internal discussions to bring members up to date with some important aspects of the association's work, and to get their input into the future strategy of ECHAMP.

The second day started with a special seminar on the situation for homeopathic and anthroposophic medicinal products in the Nordic countries. The session was chaired by Thomas Kjaersgaard, member of the Board of Management of ECHAMP, and managing director at BioVita, Denmark. The expert panel included Dr Steffen Bager, of the Danish medicines agency, Dr Sandra Holt, of the Swedish Medicinal Products Agency, and industry representatives: Klaus Sall, Danish Homeopathic Association; Sven Backlund, Swedish Manufacturers Association; Camilla Molander Ruuttu, Circlum Farmasia in Finland and Torleiv Holst, Norges NaturmedisinSentral, Norway.

The event finished with the Membership Assembly itself, also chaired by Thomas Kjaersgaard. Members were presented with a summary of work in 2011, and plans for 2012, and voted on the budget for the coming year.

The ECHAMP office team

From left to right: Amandine Oset, Christine Marking, Karen Chapman, Nand De Herdt

ECHAMP Membership Assembly, Copenhagen 2012

Publications

ECHAMP continues to provide extensive and up-to-date information on the legal and regulatory situation of homeopathic and anthroposophic medicinal products in Europe through its website, brochures, publications, reports and the regular ECHAMP e-News. Additional information, including news updates, is available to Full Members on a dedicated part of the website.

The Association

In 2012, ECHAMP welcomed a new Member, Phönix Laboratorium, bringing its membership to a total of 45 Full Members from 17 Member States, as well as 14 Corresponding Members and 10 Associated Members.

ECHAMP is also pleased to announce that former Board members Christa Hebisch and Max Daege have been appointed Honorary Members of ECHAMP in recognition of their involvement and support of ECHAMP over many years. ■

ECHAMP is the European association of companies that work closely together to ensure that its members can meet the demand from users and prescribers across the EU for homeopathic and anthroposophic medicinal products. It advocates in favour of an appropriate and well-balanced regulatory environment for these products in the EU.

ECHAMP E.E.I.G.

Rue Gray 100
B-1040 Brussels

Tel. : (32) 2 649 94 40
Fax : (32) 2 649 41 77

office@echamp.eu
www.echamp.eu