ANNUAL REPORT 2013

European Coalition on Homeopathic and Anthroposophic Medicinal Products

ECHAMP

Cover: Arnica Montana, a widely used homeopathic medicine

“Regulation is the limiting factor between the strong demand for these products, made visible across the EU, and true patient choice.”

Dr Gesine Klein, President, ECHAMP, January 2014

PRESIDENT'S STATEMENT

For a number of reasons, 2013 was a significant year for ECHAMP. A major milestone was achieved with the launch of ECHAMP's new report, 'The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU'. For the first time, an up-to-date and objective analysis of the availability of these products was presented to officials from the European Commission, Members of the European Parliament and regulatory authorities, as well as to stakeholders in the field. The facts are now all on the table; this report marks an important step towards suitable regulation of homeopathic and anthroposophic medicinal products in the EU.

The message is very clear: after 50 years of medicine regulation in the EU and 20 years of regulation on homeopathic medicinal products, the availability of these products is not sustainable and users' demand cannot always be met. Regulation is the limiting factor between the strong demand for these products, made visible across the EU, and true patient choice.

How can it be, that after 20 years, suitable regulation is still not in place across the EU?

Homeopathic and anthroposophic medicinal products have specificities that need to be considered in the rules and their implementation. To date, the implementation and enforcement of European medicines legislation for this sector has been slow and is very incomplete. Divergent implementation, interpretation and enforcement policies in the Member States make it extremely difficult to operate across Europe. The regulatory environment, including assessment capacity and policy at national level, is not proportionate to the large range of stocks and multiple finished medicinal products produced from these stocks.

ECHAMP's mission is to enable our members to meet the demand from users and prescribers across the EU for homeopathic and anthroposophic medicinal products. Suitable regulation is urgently needed to ensure proper and sufficient availability, so as to guarantee real choice for Europe's citizens.

Where next?

Homeopathic and anthroposophic medicinal products are a well-established European reality. ECHAMP believes that the various regulatory bodies at both EU and Member State level have the responsibility to foster suitable regulation for these products.

The Commission has suggested it may be worth exploring a three-step bottom-up approach, starting with better enforcement, then better guidance and if necessary suitable legislation.

In order to make substantial progress, it will be necessary for the European Commission to put the topic 'Suitable regulation of homeopathic and anthroposophic medicinal products' on its agenda for 2014-2019.

A significant first step could be a workshop amongst regulators and concerned stakeholders to table the difficulties and to agree jointly on a road map.

New ECHAMP leadership

From an internal perspective, too, 2013 was a significant year. In July 2013, Christiaan Mol and I took over the leadership of ECHAMP, as General Secretary and President. We would like, once again, to express our gratitude to our retiring President and friend Nand De Herdt for his many years of hard work at the helm, and to all who have supported this 'changing of the guards'. The new team has settled in and is well supported by the whole Board of Management.

We look forward to carrying out our duties with perseverance, so that we can meet the demand from patients throughout the EU. ■

Dr Gesine Klein, President, ECHAMP

POLITICAL ACTIVITY

In 2013, ECHAMP took many concrete initiatives to bring the difficult regulatory situation of homeopathic and anthroposophic medicinal products directly into the view of the EU policy and decision makers. Bit by bit, the issues are being heard at the highest level.

European Commission

■ **Health Commissioner Tonio Borg:** In March, ECHAMP met Health Commissioner Tonio Borg and Deputy Head of Cabinet Nils Behrndt. Our aim was to win the Commissioner's support for a more appropriate and less cumbersome regulatory environment for our products.

Commissioner Borg demonstrated a strong interest in the large and increasing demand for these products and the reasons for the lack of enforcement of existing regulation. His view is that most of the problems faced by ECHAMP members relate to the enforcement rather than the content of the regulation. He therefore suggested it might be more helpful to explore possibilities to relieve the administrative burden of the responsible authorities at Member State level rather than to change the legislation.

■ **Rossella Delfino, DG Sanco:** In October, we were pleased to meet Rossella Delfino, member of the Cabinet of the Health Commissioner Tonio Borg, responsible for medicinal products. The meeting followed up on the meeting with the Commissioner, focusing on the need for a substantial improvement of the current regulatory framework, and a three step approach to improve the regulatory environment - better enforcement, better guidance and suitable legislation.

Specific attention was given to the difficulties faced by ECHAMP members in relation to the renewal process in Italy and the high costs of pharmacovigilance fees proposed by the Commission. Mrs Delfino agreed to continue the dialogue on these and other issues affecting the sector.

"It is a European priority to cater for the freedom of choice of patients and prescribers. There is an urgent need to ensure availability of homeopathic and anthroposophic medicinal products."

Dr Thomas Ulmer MEP

In March, ECHAMP met Tonio Borg, European Health Commissioner

European Parliament

■ **Interest Group 'MEPs for CAM':** In June, MEPs Alojz Peterle and Sirpa Pietikäinen hosted a meeting of the European Parliament Interest Group 'MEPs for CAM' on the topic 'Complementary and Alternative Medicine (CAM): An investment in health.' Health Commissioner Borg, providing the keynote speech, underlined his interest in and support for CAM. Other speakers outlined the role of CAM in health care and its relevance to the EU's current policy document, 'Investing in Health'. Nand De Herdt, then

Thomas Ulmer MEP hosts event on availability in the European Parliament

ECHAMP President, spoke on behalf of ECHAMP, underlining the importance of availability of homeopathic and anthroposophic medicinal products in order to cater for patient choice.

■ **Lunch debate on availability:** In November, a lunch debate in the European Parliament hosted by Thomas Ulmer MEP was the occasion for the launch of ECHAMP's report, 'The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU' *(see page 6)*. The meeting sought to raise awareness of the urgent need to ensure availability of these medicinal products. It set the report within the context of the European Commission's priorities, defined current barriers to availability and explored EU-wide solutions.

Speakers included ECHAMP President Gesine Klein, presenting the report, Tapani Piha from the European Commission and Laurence Girod, Chair of the Homeopathic Medicinal Products Working Group. The debate was moderated by Nand De Herdt. Participants included relevant health stakeholders and ECHAMP Board members.

■ **Campaign against EMA pharmacovigilance fees:** Following the publication of a Commission proposal for a Regulation on the fees payable to the EMA for the conduct of pharmacovigilance activities relating to medicinal products for human use, ECHAMP held a series of meetings with the MEPs responsible for the European Parliament report on this proposal, with the aim of proposing concrete amendments to take account of the specific situation of our industry and its products. Meetings with relevant Commission officials also took place.

ECHAMP's legal view is that a part of the proposals as they stand is not legal and would seriously damage ECHAMP member companies by the introduction of inapplicable fees for homeopathic medicinal products authorised according to Article 16(2).

Comments and consultations

■ **Investing in health:** In May, ECHAMP submitted comments on the European Commission document, 'Investing in Health.' We underlined the positive role for homeopathy and anthroposophic medicine in obtaining efficiency gains; these medicinal products are highly sustainable from an environmental, economic, safety and public health perspective. They are also an alternative to strong, often costly prescription medicines with their many negative side effects, bringing positive effects in terms of patient safety, better health outcomes and cost saving.

■ **Reforming the internal market:** In July, ECHAMP responded to a consultation on the regulatory barriers to the effective functioning of the internal market for industrial products. We underlined the lack of harmonised implementation, interpretation, resulting guidance environment and enforcement of Directive 2001/83/EC and Directive 2003/63/EC, resulting in restricted availability of homeopathic and anthroposophic medicinal products in many Member States; ECHAMP called for a harmonised situation for these products. ■

Homeopathic and anthroposophic medicinal products are highly sustainable from an environmental, economic, safety and public health perspective.

Substantial steps are still needed to achieve harmonisation of EU legislation, its interpretation and enforcement

One of ECHAMP's main goals is an appropriate regulatory environment for our products. In 2013 we were very busy, with several publications, consultations and activities with impact on our field.

Why is progress so cumbersome?

Homeopathic and anthroposophic medicinal products have specificities that need to be considered in the rules and their implementation: they stimulate the patient's own natural self-healing potential. Pharmaceutical legislation was for the most part conceived for substances that interfere directly with body functions. In regulations, this results in a gap between the different approaches, that needs to be bridged step by step.

Variations

This year, the new variations guideline was published, combining updated versions of the former procedural and classification guidelines into one document. The new guideline applies to homeopathic medicinal products *authorised* according to Article 16.2, but not to those *registered* under Article 14. ECHAMP's proposals for specific solutions for these products, submitted in 2012, were not taken into account.

Safety: an appropriate definition of 'first safe dilution'

The Homeopathic Medicinal Products Working Group of the Heads of Medicines Agencies (HMPWG) has yet to answer the detailed comments submitted in 2012 by ECHAMP on the subject of First Safe Dilution. In 2013, ECHAMP submitted further comments to the HMPWG on this topic. We have severe concerns about the calculation basis used by HMPWG, firstly because the safety factors used for homeopathic dilutions are more restrictive than those for herbal medicinal products and secondly because they combine several safety factors from different sources, resulting in quite high first safe dilutions. It is likely that these results will have a negative impact on the simplified registration and therefore on availability.

Justification of homeopathic use

In 2013, the HMPWG published a second list of substances with justified homeopathic use and an answer to the stakeholder comments on the first list. ECHAMP will give its comments.

Braille

In its recent Notice to Applicants Volume 2a, the European Commission states that Braille is mandatory for homeopathic medicinal products registered via simplified registration procedure (Article 14). Based on legal expertise, ECHAMP is advocating the position that this requirement is contradictory to the provisions of European pharmaceutical law, as well as to current practice in the majority of Member States.

HMPWG hearing

In November, ECHAMP was pleased to attend a hearing of the HMPWG, along with other stakeholders, and to have the opportunity to express its position on a number of key topics, including recent HMPWG documents, mutual recognition, availability, future topics and our expectations of HMPWG.

Outlook for 2014: perseverance and determination

ECHAMP's work in 2013 shows that although homeopathic and anthroposophic medicinal products are an issue in national regulatory agencies, substantial progress is still needed to achieve a suitable regulatory environment, including harmonisation, common interpretation and appropriate enforcement. In 2014, ECHAMP will continue to work hard to position itself as a stakeholder to be reckoned with and an ever stronger voice for its members, so as to achieve better regulation of both simplified registration and marketing authorisation of these products. ■

ECHAMP hopes that a regular dialogue with EDQM will bring progress and mutually satisfactory solutions

In 2013, ECHAMP continued its work to foster progress in the field of the Pharmacopoeia, which is a key instrument to ensure high quality standards for users and transparency for the public.

A substantial part of this work involves communication, exchange of views, and the development of ideas and strategies. Progress can be very slow; contributors come from a wide range of backgrounds - industry, academics and authorities. For the most, pharmaceutical technical standards are first developed by those close to production and market needs, often experts from ECHAMP member companies. Then they are made public in private publications. Often there is a further phase of growth and maturation, before incorporation into an official Pharmacopoeia.

ECHAMP continues its pharmacopoeia activities on a number of different fronts

European Pharmacopoeia

The ongoing work to integrate homeopathic manufacturing methods from the German Homeopathic Pharmacopoeia into the European Pharmacopoeia continued in 2013, with a focus on the method concerning the so-called 'LM potencies'.

National pharmacopoeias

■ **Swiss Pharmacopoeia (Ph. Helv.):** An important breakthrough for integration was achieved with the publication, in seven pages, of the manufacturing methods of anthroposophic preparations in the Ph. Helv. A considerable number of these are correctly considered 'homeopathic', confirming that homeopathic and anthroposophic medicines share basic pharmaceutical characteristics.

■ **German Pharmacopoeia (DAB):** Work continued on the integration of anthroposophic substance monographs into the DAB (not to be confused with HAB, the German Homeopathic Pharmacopoeia). The DAB Commission was given a working list of proposed monographs to be included.

Anthroposophic Pharmaceutical Codex

Intensive work was carried out on the third edition of the Anthroposophic Pharmaceutical Codex (APC), now ready for publication in January 2014. The APC is published by the International Association of Anthroposophic Pharmacists and acts as an important resource for developments in official national Pharmacopoeias.

EDQM

A number of monographs have been published by the European Directorate for the Quality of Medicines & HealthCare (EDQM) and commented on by ECHAMP experts: Agaricus phalloides, Petroleum rectificatum and Staphysagria for homoeopathic preparations.

ECHAMP fully acknowledges the progress made by EDQM in this field, and the importance of its future programme. However, controversial discussions, with science-based arguments, need to continue in order to foster progress: in particular on the topic of 'assays'. In October, EDQM's technical 'Guide for the elaboration of monographs on homoeopathic preparations' stated that assays shall be required 'if necessary'. ECHAMP's view is that quality cannot be ensured by quality control alone, but is generated by substantial investment in manufacture. Quality control should constitute substantial added value to the substance, preparation or product concerned.

ECHAMP hopes that a regular dialogue with EDQM will bring progress and mutually satisfactory solutions so as to ensure the quality of the considerable number of homeopathic preparations. ■

AVAILABILITY: NEW ECHAMP REPORT

A new report has been published by ECHAMP, 'The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU,' providing an up-to-date and objective analysis of the status and deficits of availability of homeopathic and anthroposophic medicinal products in the EU.

This comprehensive report provides recent information on the demand for and availability of these products. It identifies causes for lack of availability in the different Member States, analyses the status of implementation of EU pharmaceutical legislation and the application of regulatory requirements at national level and assesses the impact on availability.

The report was prepared in cooperation with PricewaterhouseCoopers (PwC). It draws on a variety of sources – firstly pan-European socio-economic, sales and demand data relating to health care provision; secondly regulatory data collected from the websites of the medicines agencies, and the findings of a first independent survey by PwC (27 national medicines agencies); and finally the findings of a second independent survey by PwC to test the reality of the availability of homeopathic and anthroposophic medicinal products in a quantitative and a qualitative way at the point of delivery of medicinal products to the citizens.

The types of products most widely available in pharmacies are those requested for self-medication.

Suitable regulation is urgently needed to ensure proper and sufficient availability, so as to guarantee real choice for Europe's citizens

Findings

The main findings of the report can be grouped around five main headings:

- **Demand:** There is significant to high demand for homeopathic and anthroposophic medicinal products in at least two thirds of EU Member States, and this applies to countries both with and without a long-term tradition for these products.

- **Availability:** Availability of registered/authorised homeopathic and anthroposophic medicinal products in the EU is insufficient and the demand cannot always be met. The types of products most widely available in

pharmacies are those requested for self-medication.

■ **European legislation:** Implementation and enforcement of European medicines legislation for this sector has been slow and is very incomplete even twenty years after its adoption. Divergent implementation, interpretation and enforcement policies in the Member States make it extremely difficult for companies to operate across Europe.

■ **Regulatory environment:** The regulatory environment, including assessment capacity and policy at national level, is not proportionate to the large range of stocks and multiple finished medicinal products produced from these stocks, which are used in homeopathic and anthroposophic therapy. In many Member States the number of registered products poorly reflects the high numbers of homeopathic prescribers.

■ **Sustainability:** Availability is threatened in some Member States by the lack of a registration process, and in others by an incomplete process for the renewal of existing registrations.

The regulatory burden is such that it is not sustainable to maintain registrations for the full range of medicinal products required for proper practice of these therapies.

Conclusions

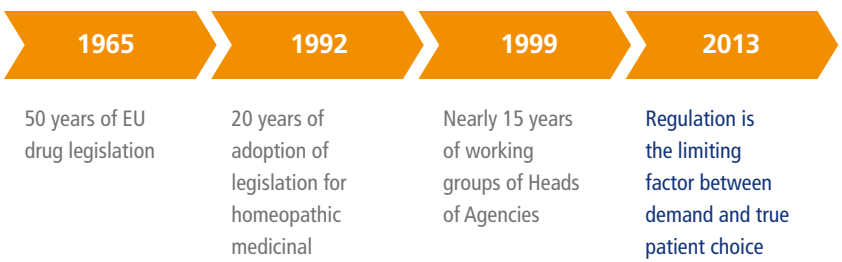
It is clear from the findings of the report that suitable regulation is urgently needed to release the bottleneck between demand for homeopathic and anthroposophic medicinal products and ensuring proper and sufficient availability, so as to guarantee real choice for European citizens.

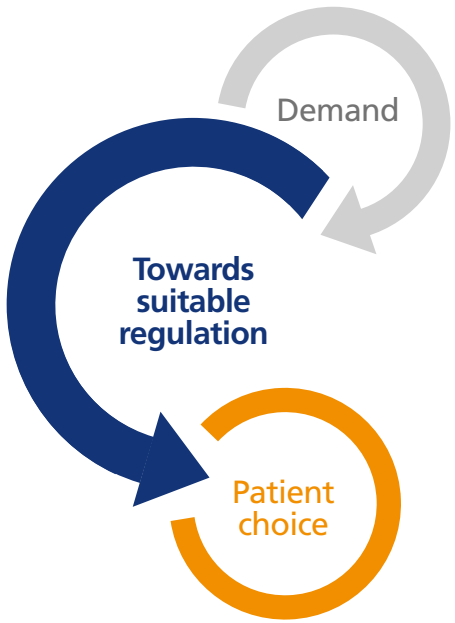
Adequate solutions must improve and simplify the situation for homeopathic and anthroposophic medicinal products in the EU.

As regards Article 14 products (registered products), it will be essential to limit the administrative burden and reduce the efforts required to a level which is proportionate to the purpose. In addition, the clearly visible demand for OTC and self-medication products will need a more harmonised regulatory approach and assessment policy for authorised products (Article 16.2). And finally, solutions are needed to meet the growing demand for anthroposophic medicinal products.

ECHAMP calls on the EU – that is, the European Parliament, the European Commission and the Member States - to acknowledge this priority and to work together, with industry, to find a viable, effective and appropriate solution for these long-standing, traditional, safe and effective products. ■

The report was launched at a lunch debate in the European Parliament hosted by Thomas Ulmer on 27 November. A full copy of the report, a summary version and the launch presentation can be downloaded from the ECHAMP website.

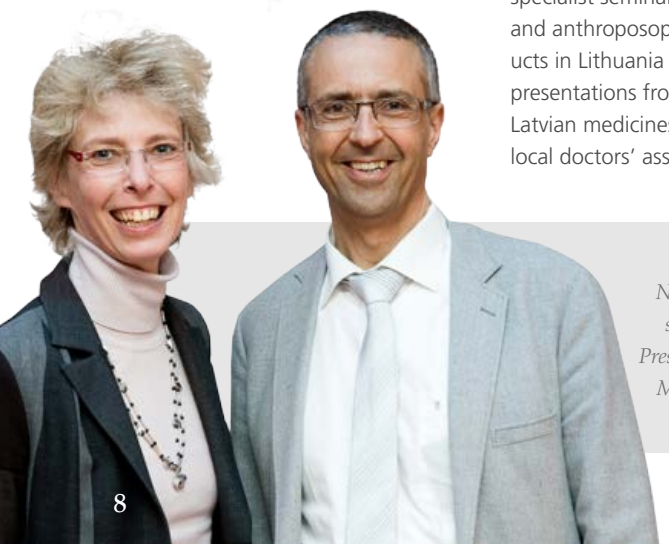




Visit www.echamp.eu for detailed information on issues affecting our sector at European level

Membership Assembly 2013

ECHAMP's annual Membership Assembly was held in Vilnius, Lithuania in April, chaired by local Member, Ineke Bos, of UAB Mitela. Members agreed the budget and plans for the coming year. The event included a specialist seminar on homeopathic and anthroposophic medicinal products in Lithuania and Latvia, with presentations from the Lithuanian and Latvian medicines agencies and the local doctors' associations.



New ECHAMP leadership: Dr Gesine Klein, President and Chrisitaan Mol, General Secretary

Fausto Panni, President of Omeoimprese, the Italian association of homeopathic and anthroposophic companies, and chief executive of Wala Italia S.r.l, was elected Chair of the next annual Membership Assembly, to be held in Rome in April 2014.

New leadership

In June, Nand De Herdt retired as President after 14 years' close involvement with ECHAMP. Dr Gesine Klein was appointed as new President of ECHAMP and Christiaan Mol as General Secretary. Both are long-time Board members of ECHAMP.

Publications

ECHAMP makes widely available detailed information on issues affecting our sector at European level through its website, quarterly ECHAMP e-News and other publications and reports. This year saw the launch of a new report 'The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU', and the publication of a new introductory brochure: 'Homeopathic and Anthroposophic Medicinal Products – a thriving European tradition.' Both documents are available on the ECHAMP website. In addition, ECHAMP offers exclusive information to members through special additional news services and its website.

The association

ECHAMP now has about 50 Full Members from 17 Member States, as well as 13 Corresponding and 10 Associated Members. ■

ECHAMP Membership Assembly, Vilnius, 2013

Nand De Herdt

ECHAMP, the European Coalition on Homeopathic and Anthroposophic Medicinal Products, 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 regulatory environment for these products in the EU.

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