ANNUAL REPORT

2014

European Coalition on Homeopathic
and Anthroposophic Medicinal Products

ECHAMP

"This sector contributes viable, affordable and sustainable healthcare solutions – now it's time for the EU institutions to finally solve the regulatory contradictions in our sector."

Dr Gesine Klein, President, ECHAMP, January 2015

2015: NEW COMMISSION, NEW PARLIAMENT – A NEW START?

The appointment of a new European Commission and the election of a new European Parliament heralded in many new faces in Brussels in 2014. But national health policy actors, in particular the health ministries, often pursue national preferences. What opportunities do these changes bring for a fresh approach to the EU industry for homeopathic and anthroposophic medicinal products?

There are many areas of EU health policy for which these products have much to offer in response to health challenges.

EU health policy prioritises patient safety and patient choice: long-term experience demonstrates that these medicines have a high safety profile, with few adverse reactions and very rare serious adverse reactions. The users greatly appreciate the product safety. Recent market studies show increasing numbers of Europeans are turning to these patient-centred therapies.

These medicines also address the need for greater effectiveness and cost-effectiveness – a significant number of clinical studies show that homeopathy and anthroposophic medicine work and observational studies consistently demonstrate real-world effectiveness, showing major improvements for quality of life. These products can help address the challenge of an ageing population and the increasing number of older people in need of treatment for a wider variety of conditions. The products themselves are normally less expensive than conventional medicines, and it is plausible to state that homeopathy and anthroposophic medicine can contribute to sustainable health systems by reducing direct, indirect and intangible healthcare costs.

There is a further opportunity for investigation by the EU into new solutions for the problem of antimicrobial resistance and the urgent need to reduce dependency on antibiotics. Homeopathy and anthroposophic medicine offer effective treatment options for a range of infectious human diseases, and an alternative to antibiotic use in animal husbandry.

European institutions are slowly becoming aware of the opportunities our sector affords. But they seem to lack the courage to endorse the innovation that homeopathic and anthroposophic medicines offer. We see very few signs that they are even able to acknowledge the needs of this Europe-specific industrial resource, let alone support it or help it to develop. The increasing regulatory burden cannot be justified for products which have been safely on the market for decades, with long-established use by doctors and patients. Substantial progress is still needed to ensure that these products can be and remain properly available in all Member States.

In 2014, it became increasingly clear that decisions taken at European level in the name of harmonisation result in regulations that are partly non-practicable or do not add any value for these products. There are even tendencies for interpretations to be published which go beyond existing EU Directives. The availability of the products and the very industry itself are at risk as the bureaucratic and economic burden continues to grow on the back of users and industry.

In this, ECHAMP's fifteenth anniversary year, as we look back over 15 years of increasingly difficult conditions for our sector, we continue to face many of the same challenges that brought the association into being.

Homeopathic and anthroposophic medicines work. They help people, have few side effects, and are cost-effective and environmentally friendly. ECHAMP remains confident that this sector contributes viable, affordable and sustainable solutions to many of the health challenges faced by the EU. We will continue to work to safeguard and grow our sector. But we have to ask – when will the EU institutions acknowledge the challenges we face? It's time to finally solve the regulatory contradictions in our sector. ■

Dr Gesine Klein, President, ECHAMP

The new publication gives significant prominence, for the first time, to the situation concerning the availability of these products in the EU

Changes in Brussels in 2014 brought about a new context and some good opportunities for ECHAMP.

European Commission

ECHAMP warmly welcomes the publication of the 'External Study Report on the Availability of Medicinal Products for Human Use,' which gives significant prominence, for the first time, to the situation concerning the availability of homeopathic and anthroposophic medicinal products in the EU.

This publication arrives at an interesting time: in October former Lithuanian health minister, Vytenis Andriukaitis, was appointed Commissioner in charge of health and food safety, with Elżbieta Bieńkowska taking charge of DG Growth and Frans Timmermans of the new post on Better Regulation. ECHAMP wrote to the relevant appointed Commissioners to introduce the need to address the issues faced by our industry as a matter of urgency.

In addition, we wrote to previous Health Commissioner, Tonio Borg, before the end of his term of office, to ensure that the need to address the barriers and challenges facing our area would be included in the 'legacy' dossier that was being prepared for the new Commissioner.

In the Member States

ECHAMP's experience in 2014 once again confirmed that although a number of officials in the European Commission and Members of the European Parliament listen carefully to us and endorse helpful actions, the Member States hold significant influence on EU policy making for our sector. We are dedicating our attention to policy making in Members States at political as well as regulatory level. As well as the Ministries of Health, there is a growing role for the regions in endorsing innovative health policies.

■ **Activity in Italy:** This was confirmed in April, at an ECHAMP seminar in Rome on 'The status of

'The status of homeopathy and anthroposophic medicine in Italy', ECHAMP seminar, Rome, April 2014

Vytenis Andriukaitis, new Commissioner for health

homeopathy and anthroposophic medicine in Italy,' which gave a platform to national and regional Italian officials and politicians during the Italian Presidency of the EU. Hosted under the patronage of the Region Lazio, and co-organised with Omeoimprese, the Italian manufacturers' association, the seminar showed that, despite regulatory difficulties for these products, a bottom-up approach is driving the awareness and availability of homeopathy and anthroposophic medicine in Italy. The presentation of the Tuscany model for integration of homeopathy in regional healthcare confirmed the positive cost-effectiveness profile of these therapies as well as patient satisfaction.

European Parliament

In May, ECHAMP developed a Manifesto for the European Parliament elections, introducing potential, new and re-elected MEPs to the benefits and challenges of the industry for homeopathic and anthroposophic medicinal products. We called for suitable regulation to ensure proper and sufficient product availability of these products and to guarantee real health choices for the millions of users.

ECHAMP wrote to all elected MEPs in June, following up in September with a request for support from the members of the three Committees of most relevance to ECHAMP's work, ENVI, IMCO and ITRE. ECHAMP members also made contact with local MEPs, to introduce their individual companies.

■ **Parliamentary Questions:** A number of MEPs tabled relevant Parliamentary Questions during the year. **Thomas Ulmer MEP** tabled a question on the availability of homeopathic and anthroposophic medicinal products, asking whether existing legislation should be amended or a separate regulatory framework for these products should be developed. The Commission replied that there are no plans to amend Directive 2001/83 /EC or to develop a separate EU legislation for the sector.

Marian Harkin MEP asked whether Member States would introduce or retain specific rules for preclinical tests and clinical trials of homeopathic products. In its reply the Commission referred to EUR-Lex website and the authorities of the Member States.

Alojz Peterle MEP asked about progress of the 'Cyprus clause,' in relation to homeopathic medicinal products, which, under certain conditions, would allow a Member State to place on the market a medicinal product authorised in another Member State; the Commission replied that its pending report on the availability of medicinal products will address the implementation of Article 126a, originally due before 2008.

Policy responses

In 2014, ECHAMP responded to a number of Commission papers:

■ **Effectiveness, accessibility and resilience:** In its response to the Commission *Communication on effectiveness, accessibility and resilience for EU's health systems* in April, ECHAMP focused on the positive contribution of our products and the need for patient choice and self-management, availability, increased health research efforts in our field and integrated healthcare systems, supporting choice, safety and cost-effectiveness.

A growing number of patients actively choose these products for their health care

■ **Quality of health care:** In August, ECHAMP responded to the draft Opinion of the *Expert Panel on Effective Ways of Investing in Health*, which noted that all health services should be effective, safe, appropriate, patient-centred and equitable. We showed how our sector supports these aims – through the quality, safety, effectiveness and cost-effectiveness of our products, the patient-centred nature of our therapeutic systems and the growing number of patients who actively choose these products for their health care.

■ **The pharmaceutical sector:** ECHAMP responded to the Commission Staff Working Document, *The pharmaceutical sector: a strategic sector for the European economy* pointing out that it focuses only on the allopathic pharmaceutical industry and does not take account of the increasing choice of patients to use homeopathic and anthroposophic medicinal products, and the contribution these products can make to addressing current health challenges. ■

If the specificities of this sector continue to be neglected, dissatisfaction will increase, products will disappear, and a grey or black market is likely to develop

One of ECHAMP's main goals is to achieve an appropriate regulatory environment for homeopathic and anthroposophic medicinal products. In some Member States, reasonable and proportionate regulations do exist, leading to national registrations and guaranteeing the availability of homeopathic and anthroposophic medicinal products. In 2014, it became increasingly clear that decisions taken at European level in the name of harmonisation result in regulations that are partly non-practicable or do not add any value for these products. There are even tendencies for interpretations to be published which go beyond existing EU Directives.

HMPWG

Much effort was focussed throughout the year on reacting to the publications of the Homeopathic Medicinal Products Working Group of the Heads of Medicines Agencies (HMPWG). This group is extremely short of resources and thus unable to implement working standards expected from other institutions. Nevertheless, it remains one of ECHAMP's most important stakeholders.

- **Justification of homeopathic use:** There are now three lists, with a total of 125 stocks, for which HMPWG considers the use in homeopathy as justified. In its comments, ECHAMP emphasizes that homeopathic stocks from all homeopathic traditions in Europe must be included in a fair and transparent way. This means that data from national registrations and literature should be taken into account for the assessment, as well as data from commercially available databases.

- **First safe dilutions:** Since 2012, HMPWG has published calculations and definitions for the first safe dilution of a dozen homeopathic stocks. ECHAMP fully supports the need for safety of medicinal products and its members work hard to ensure that these long-established products continue to meet the highest standards of safety. With the help of toxicologists from its member companies, ECHAMP is investing a great deal of time commenting on HMPWG publications on this topic. However, we are very concerned that disproportionate and overlapping safety factors are being used for the calculation of the first safe dilutions of homeopathic stocks, resulting in high theoretical first safe dilutions. These will have to be adjusted individually by the applicants for each registration dossier. This is in contradiction to the original intention of the

These long-established products continue to meet the highest standards of safety

concept of first safe dilution, which was to reduce the workload during registration for all stakeholders. There is an additional risk that the medicines agencies will consider the first safe dilutions as absolute values, and it is likely that this issue will have a negative impact on the availability of homeopathic medicinal products in the Member States.

Pyrrolizidine alkaloids

ECHAMP commented on the *Second public statement for herbal medicinal products* from the Committee on Herbal Medicinal Products (HMPC) regarding the limit of pyrrolizidine alkaloids, identifying the consequences of the proposed limit for homeopathic and anthroposophic medicinal products.

Braille

In its Notice to Applicants Volume 2a, the European Commission states that Braille is mandatory for homeopathic medicinal products registered via simplified registration procedure (Article 14). This is despite the fact that practical solutions for this issue are already in place in most Member States. ECHAMP wrote to the European Commission and HMPWG explaining why this requirement is contradictory to EU Directive 2001/83/EC. This is an example of how confusion is created between EU institutions and national policies: well-established practices are contradicted 'overnight,' creating divergence between practice and norms.

Risk Management Plans

The European Medicines Agency (EMA) requires Risk Management Plans (RMPs) for new applications of Article 16.2 products. ECHAMP wrote to the EMA drawing attention to the disproportionate administrative effort needed for our products, and questioning the additional benefit of RMPs for these products, which have been safely on the market in EU Member States for decades. We proposed that homeopathic medicinal products should be exempt from the duty of submitting them. To date there has been no response, although we know that EMA is working on this topic.

In the Member States

■ **Italy:** In Italy, the transition period for renewal of currently notified homeopathic medicinal products ends in 2015. ECHAMP provided support to its member companies and Italian associated members on open issues such as registration requirements, timelines and fees; we helped with personal and written communication with the Italian medicines agency, the Ministry of Health and the European Commission.

■ **Spain:** At the end of 2013, a draft ministerial order was published in Spain regarding the homeopathic medicinal products notified in 1995 which still need be registered. ECHAMP sent in comments, emphasising the need to implement appropriate registration procedures for all notified homeopathic medicinal products. The final ministerial order has not been published and it is yet to be seen what impact the legislation will have on the availability of homeopathic medicinal products on the Spanish market.

Justification of use lists must include stocks from all homeopathic traditions in Europe

Outlook for 2015: need for a fair sector agreement

Substantial progress is still needed in the European regulatory environment to ensure that homeopathic and anthroposophic medicinal products can continue to be available in the Member States. Regulatory affairs are a service to society providing legal certainty to users and stakeholders. Each sector has specificities. Good regulatory guidance and practice reflect a sector agreement. If the specificities of this sector continue to be neglected, dissatisfaction will increase, products will disappear, and a grey or black market and informal governance are likely to develop. ■

Quality standards in the pharmacopoeias bring recognition to and help create a legal frame for our products

Quality standards in the pharmacopoeias are important, as they bring recognition to and help create a legal frame for homeopathic and anthroposophic medicinal products. This gives a solid basis on which to submit dossiers for a marketing authorisation or registration, and gives the authorities a binding legal instrument by which to review the quality.

In addition to its pharmacopoeial work, ECHAMP seeks a regular dialogue with the European Directorate for the Quality of Medicines & Health-Care (EDQM) and hopes that the views and expertise of its members will support this valuable work.

Belladonna for homeopathic preparations, a priority substance with toxic components

A specific general monograph for minerals and one for salts for homeopathic preparations is now needed

European Pharmacopoeia and EDQM

The European Pharmacopoeia (Ph. Eur) provides official standards for the manufacture and quality control of medicinal products in all its signatory states. In 2014, work continued in the Homeopathic Manufacturing Methods Working Party (HMM WP) and the Homeopathic Working Party (HOM WP), which elaborates monographs on the substances used for homeopathic preparations.

In 2014, HOM WP acquired a new chair, Professor Michael Keusgen, who calls on authorities and industry to help speed up the process of elaborating monographs.

HMM WP finished the monograph for pillules for homeopathic preparations and published it for comment in Pharmeuropa. The manufacturing methods, decoctions and infusions, have been worked out and will be published in 2015. An important decision was made to adopt the LM potencies. The Working Party is also working on the 46 priority substance monographs of inorganic substances and substances with toxic components. Belladonna for homeopathic preparations was published in Pharmeuropa for comments.

Other important topics were the microbiological requirements of raw materials, intermediates and finished products for the manufacturing of homeopathic preparations. The monograph 'Substances for pharmaceutical use' was analysed in relation to homeopathic preparations.

In future, Ph. Eur intends to make a cross reference in this monograph and in the one on 'Pharmaceutical preparations' to a new guideline on elemental impurities. The HOM WP therefore decided that a general monograph on minerals and one on salts for homeopathic preparations should be elaborated in analogy to the general monograph 'Herbal drugs for homeopathic preparations.' This work is a challenge because the world of minerals needs special knowledge to propose quality tests and specifications.

Anthroposophic Pharmaceutical Codex

The 3rd edition of the APC was published in 2014. It describes the main anthroposophic manufacturing methods not described in any official pharmacopoeia of the EU Member States (although the Pharmacopoeia Helvetica does include them) and the substances used in anthroposophic medicine with a reference to other Pharmacopoeias where possible. The document can be a basis for the legal inclusion of anthroposophic medicinal products especially for those that are not manufactured according to a homeopathic manufacturing method. ■

Homeopathy and anthroposophic medicine can help reduce dependency on antibiotics in humans and in animals

Sirpa Pietikäinen MEP, chair of 'MEPs for CAM'

MEPs for CAM

'MEPs for CAM' is an informal group of Members of the European Parliament that aims to put and keep complementary and alternative medicine (CAM) on the EU policy agenda.

One meeting was held in 2014, 'CAM: reducing the need for antibiotics'. It was hosted by MEPs Sirpa Pietikäinen and Alojz Peterle. In view of the urgent need to reduce the use of antibiotics, the meeting focused on evidence that some CAM disciplines, including homeopathy and anthroposophic medicine, offer effective treatment options for a range of infectious human diseases and can significantly reduce dependency on antibiotics; they also offer an effective alternative to antibiotic use in animal husbandry. They must therefore be seriously considered and investigated by the EU, for both human and animal health.

'MEPs for CAM' is being re-established following the European elections earlier this year and will be chaired by Sirpa Pietikäinen MEP.

EUROCAM activities

EUROCAM is the alliance of European umbrella organisations of patients, physicians and practitioners in the field of complementary and alternative medicine (CAM), aimed at promoting the contribution of CAM to better health in Europe. It provides the secretariat for the CAM Interest Group.

In 2014, EUROCAM published two important documents: *'CAM 2020: The contribution of Complementary and Alternative Medicine to sustainable healthcare in Europe,'* which outlines the current practice and availability of CAM as well as its potential future role in contributing to the healthcare of citizens across the EU; and *'The role of Complementary and Alternative Medicine in reducing the problem of antimicrobial resistance.'* The report reviews the evidence for the use of CAM therapies in this area, including homeopathy and anthroposophic medicine, and calls for further research to determine for which conditions, in both human and veterinary healthcare, specific CAM disciplines are particularly effective.

EUROCAM's manifesto for the European elections was sent to all elected MEPs, outlining the need for the EU to take action in this area, as well as calling on them for support and participation in the CAM Interest Group.

Other stakeholders

ECHAMP continues to collaborate with other stakeholders in the field of homeopathy and anthroposophic medicine developing the sector in mutual respect for the sake of a relevant contribution to medicine. ■

ECHAMP was very pleased to welcome five new Full Members in 2014

The ECHAMP team – From left to right: Amandine Oset, Christine Marking, Gesine Klein, Christiaan Mol, Karen Chapman

Membership Assembly 2014

ECHAMP's Membership Assembly in April took the association to Rome, for two full and lively days of meetings, discussions, networking and social activities.

The meeting included: an internal workshop for members, to present ECHAMP's strategy for the next five years and discuss members' involvement in making this happen; a high profile seminar on the situation of homeopathic and anthroposophic medicinal products in Italy, which received considerable press coverage in Italy; and the Membership Assembly chaired by Fausto Panni, of Italian member, Wala.

The next Membership Assembly will be held in Brussels in April 2015, and will celebrate ECHAMP's 15th anniversary. It will be chaired by Dr Norbert Schulz.

ECHAMP Membership Assembly, Rome, April 2014

Membership

ECHAMP was pleased to welcome five new Full Members in 2014 - CeMon srl from Italy, Homeo Nitra from Slovakia, Korres Natural Products from Greece, Labo'life from Spain and Labo'life from Belgium. Former President, Nand De Herdt, was also unanimously voted Honorary Member of ECHAMP.

We now have about 50 members from 19 different EU Member States, as well as 13 Corresponding, ten Associated and four Honorary Members.

Publications

ECHAMP provides a regular information service on developments concerning homeopathic and anthroposophic medicine in the EU, to members, policy makers, politicians and other sector stakeholders. Our website also provides up-to-date news and information on the sector.

In 2014, ECHAMP e-News was published three times, providing updates and food for thought, including articles by MEPs Sirpa Pietikäinen and Alojz Peterle, as well as an interview with former President, Nand De Herdt. In 2014 we published a special report on the Implementation of Article 16.2 and a summary of available literature on 'Reducing healthcare costs with homeopathy and anthroposophic medicine in Europe'. We also published a Manifesto for the European Parliament elections.

All materials are available on the ECHAMP website, which also includes a dedicated section for Full Members only, with additional internal, market and sector information and other resources. ■

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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