An evolving science

Policy makers should pay close attention to the rapidly evolving field of scientific research in homeopathy and anthroposophic medicine.

President’s statement, Dr Gesine Klein

I am pleased to present a report of ECAM’s activities and progress in 2016.

Growing numbers of users of homeopathy and anthroposophic medicine reinforce a long history of active patient choice in favour of these therapies and countless successful case studies from patients and prescribers. The well-known safety of these medicines stands in stark contrast to stories about side-effects of chemical medicines. Modern studies on cost-effectiveness generally find in favour of these gentle treatments.

Safety, quality, effectiveness and cost-effectiveness are all important criteria for EU health policy makers, and the European Union is at the forefront of defining and implementing quality standards for these products.

Outside the EU, some countries lead the way in integration of these therapeutic systems into mainstream health care: the Swiss government intends to ensure that treatment costs for homeopathy and anthroposophic medicine will continue to be reimbursed by compulsory health insurance on a par with other medical disciplines and the Indian government has set up the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) to ensure optimal development of these systems of health care.

Such decisions are based on positive economic and health experiences; these are significant developments that need to be watched closely. EU and member state policy makers should also pay attention to the rapidly evolving field of scientific research in both homeopathy and anthroposophic medicine.

In contrast to its general reputation in the media, this is a dynamic and evolving field of scientific study. Its scientists are passionate and committed to expanding the boundaries of science and of health care. This academic sector is increasingly focused on speaking with one voice and making its voice heard.

A growing body of high quality clinical evidence and rich experiments into the mechanism of action of these medicines fuel the debate about these therapies and cannot be ignored. Organisations such as Homeopathy Research Institute (HR1), Wissenschaftliche Gesellschaft für Homöopathie (WissHom) and Groupe International de Recherche sur l’Infinitésimal (GIRI) are spearheading initiatives to meet and establish the highest standards of research and to answer the most prominent questions facing the sector.

For its part, industry matches the essential research work with its own serious work to identify appropriate quality standards that satisfy the specific characteristics of these well-established medicinal products. It is committed to meeting the ever-growing demand of Europe’s citizens for these medicines and seeks to establish the retrospective scientific rationale for two hundred years of successful manufacturing and distribution of these products.

Looking forward

Governments, industry, scientists and the community of prescribers, patients and users of these medicines all have a role to play in ensuring the successful widespread availability of these medicines and therapies.

The dual expert input from scientists and industry should be embraced by policy makers to support the work they are doing to set standards and develop appropriate regulation for the sector. Without the support of a healthy regulatory governance that takes the specific characteristics of the products and the sector into due account, the sector cannot survive and thrive. Policy and decision makers have a responsibility to follow this debate in depth, to understand the evolving evidence base and the specific quality needs, and to make informed decisions based on the most accurate and up-to-date information.
Meetings with high-level Commission staff: ecHAMp made good progress in 2016 in its work to build on the meeting in 2015 with European Commissioner for Health, Vytenis Andriukaitis, at which he requested a list of regulatory problems facing our sector for which it is within the direct competence of the European Commission to act. A preliminary listing of these ‘focus points’ was provided in December 2015 to Mrs Annika Nowak, Member of Cabinet of the Health Commissioner. Following months of in depth work by technical, legal and regulatory experts from ecHAMp member companies, ecHAMp President, Dr Gesine Klein and General Secretary, Christiaan Mol, met Mrs Nowak again on 17 October to present the full list of focus points with carefully identified potential solutions. The main focus points for which it is believed the Commission has the competence to act are as follows:

- the need to clarify the definition of ‘administered externally’ as specified in Article 14 of Directive 2001/83/EC
- a request for exemption from routine pharmacovigilance documentation for products authorised in accordance with Article 16.2
- the need to determine re-test dates of intermediate dilutions or triturations in line with general pharmaceutical guidelines on stability testing and Good Manufacturing Practice
- the option to provide users with product information for homeopathic medicinal products with non-prescription status registered under the simplified registration scheme
- resolution of the contradiction for the requirement of Braille for products with simplified registration
- support for a pharmacopoeial monograph for anthroposophic medicinal products
- the introduction of adequate rules on effectiveness of anthroposophic medicinal products.

These focus points, with proposed possible solutions for the Commission, will now be transmitted to DG Santé’s technical staff for further analysis. ecHAMp will also explore further options for those regulatory barriers for which the solutions are not within the direct competence of the European Commission. As advised by the Commission, we are giving priority to a ‘bottom up’ approach, preferably seeking solutions which do not require changes to the legislation.

Responses to initiatives: During 2016, ecHAMp responded to the two final Opinions of the Expert Platform on Effective Ways of Investing in Health (Disruptive innovation and Access to healthcare in the EU), underlining the need to take more account of the potential contribution of homeopathic and anthroposophic medicine. Unfortunately, ecHAMp’s input was not included in the final versions.

New officials: ecHAMp sent welcome letters to Mr Bob Vanhoorde, the new Head of Unit ‘Medicines: policy, authorisation and monitoring’ and to Mr Dominik Schnichels, new Head of Unit for ‘Medical products: quality, safety, innovation,’ following a major restructuring of DG Santé in the spring. We introduced our industry and outlined the challenges our member companies face.
During the course of the legislative process of a new Regulation on mercury, implementing the Minamata Convention, ECHAMP worked with other associations to secure future import and export of mercury and its compounds, as used as starting material for homeopathic and anthroposophic medicinal products. Final results are expected early in 2017.

ECHAMP continued its efforts to build a solid network of ‘friends’ within the Parliament to support more effective advocacy and raise awareness amongst MEPs of the contribution and concerns of our sector. To date, efforts have concentrated on developing relations with MEPs in Spain, Italy, Germany, France and the Netherlands; a number have been willing to act as champions should relevant reports and initiatives arise. In October, activities started with members in Ireland and Sweden, and the aim is to address Bulgarian MEPs as well.

In 2016, ECHAMP continued its work to approach officials in national ministries, working in close collaboration with member companies.

Christiaan Mol was invited to speak on behalf of ECHAMP at an event hosted by the Senate of the Italian Republic, which set out diverse directions in complementary medicine, including homeopathy and anthroposophic medicine.

In a sustained joint effort with associated partner, Bundesverband der Pharmazeutischen Industrie e.V. (BPI), in Germany, we were able to communicate the value of this sector to diverse governing bodies in the state of Baden-Württemberg, one of the four ‘motors of Europe’. We informed the regional Ministry of Economic Affairs, Labour and Housing of the value of high profile business jobs in the ECHAMP companies; and the Ministry of Social Affairs and Integration of the therapeutic benefit of the products for the population. The latter contributed to the commitment by Baden-Württemberg to install a university chair on complementary medicine.

Furthermore, ‘Germany Trade and Invest,’ the agency of the Federal Ministry for Economic Affairs and Energy, has made a commitment to publish a brochure giving the German perspective on this sector; it will include contributions from ECHAMP German members, along with professionals from other associations.

Finally, ECHAMP contacted officials in ministries in Germany, Italy and Spain to inform them of the newly translated material from Homeopathy Research Institute, sponsored by ECHAMP, providing accurate and reliable information about homeopathy research (see page 7). For the first time, ECHAMP also ‘went global,’ sharing this information with the Indian Ministry of AYUSH.
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Transparency of HMPWG: formality or genuine intention?

A well-functioning regulatory environment with an efficient, transparent umbrella regulatory institution is essential if this industry is to face the growing demand for its medicinal products.

ECAMP acknowledges the work done by the Homeopathic Medicinal Products Working Group (HMPWG) within difficult organisation conditions in recent years. It is hampered by a lack of resources, particularly in comparison to equivalent bodies within the Heads of Medicines Agencies (HMA) in other sectors. At the same time, it is the only working group within HMA that develops wide guidance concerning market access, quality assurance and control for a whole sector. The documents are mostly called ‘Points to Consider,’ yet in practice, they seem to set a strict framework of guidance for the medicines agencies.

Nevertheless, the working methods and processes lack transparency as regards communication towards the stakeholders in this sector; there is no real exchange of expert opinions between company and HMPWG experts. The written consultation process does not seem to be a suitable mechanism for finding solutions which are satisfactory for all sides. A much greater degree of transparency and a much livelier forum for exchange with stakeholders are needed.

In September, ECAMP addressed these issues with HMPWG, requesting a transparency policy comparable to the one of analogous EU standard setting governing bodies. The response from the HMA simply referred us to the HMPWG mandate and rules of procedure, without acknowledging the importance of the issues raised. For ECAMP, transparency is also a matter of good will, to recognise and endorse the needs of the sector. Otherwise, the risk, as we see it, is a reduction in the value and significance of the HMPWG decisions.

Consultations from HMPWG

In 2016 as every year, regulatory and technical experts from ECAMP member companies gave full attention to responding to consultations and draft documents from HMPWG. This work demands a major investment of resources by the companies but experience has shown that our contributions are rarely accepted by HMPWG, nor do we receive explanatory feedback.

First safe dilution: At the end of 2015, HMPWG adopted a Question & Answer document on First Safe Dilution. An analysis by ECAMP shows that despite considerable effort and input, very few, if any, major stakeholder concerns were taken on board. In 2016, ECAMP also submitted comments to the consultation on a first list of first safe dilutions. ECAMP has severe concerns on the calculation basis used by HMPWG: the safety factors used for homeopathic dilutions are more restrictive than those used for herbal and traditional medicinal products; in addition, they combine several safety factors from different sources, resulting in very high first safe dilutions. This is not in accordance with the decision tree of
the Points to Consider on non-clinical safety of homeopathic medicinal products of botanical, mineral and chemical origin. It is likely the result will have a negative impact on the number of products registered through simplified registration and therefore on the availability of these medicinal products. A dedicated ECHAMP working group of toxicology experts from several member companies has been set up to focus expertise towards more satisfactory results.

Justification of homeopathic use: In June, HMPWG published a consolidated list of justified stocks combining three separately published lists and a preamble. ECHAMP was disappointed to see that there was no inclusion in this final document of the bibliographic reference used as the basis for the assessment of each stock. A fourth list was adopted in November and a fifth list released for consultation.

Safety of homeopathic medicinal products from biological origin: A revised version of the Points to Consider document was published in April; it did not include any of the 15 comments submitted by ECHAMP in 2015.

Microbial limits: In August, ECHAMP also submitted comments on a draft Points to Consider on the selection of microbial limits for non-sterile homeopathic raw materials, stocks, preparations and products.

Looking forward: what do we hope for?

ECHAMP welcomes the intention to harmonise issues, but in practice, far from bringing clarification, HMPWG statements seem to bring more complexity and greater variation of approach and interpretation.

There is a clear need for greater transparency, better communication and more fruitful exchange of views. ECHAMP also believes HMPWG could play a valuable role in the wider context of ensuring the full availability of safe, quality, licensed products on the EU market.

It would be helpful for HMPWG to publish a detailed overview of the EU situation for registration, with different country examples, to facilitate exchange of good practice.

They might also offer support or advice on the time needed for re-registration, referring to the examples of France and Germany.

Additionally, it would be helpful to develop guidelines on how existing registrations can be used for other countries; currently, when a country takes the initiative to re-register all products already on the market, the requirements often undergo a lengthy review, resulting in formalities that do not add to the quality or safety of the products. This approach is not suitable for products which have been on the market for decades, often already registered in other member states; it may not even be within the intention of the law. Such guidelines could limit the workload for agencies and industry alike.

ECHAMP both needs and wishes to support a further development of HMPWG; we are ready and willing to invest all efforts to help bring these ideas to fruition.
In 2016, experts from ECHAMP member companies, mainly from France, Germany, Italy and Switzerland, invested considerable time to bridge the gap between different European traditions as regards quality criteria for homeopathic raw materials and stocks. As a first step, their focus was on plant materials and preparations.

This is a critical moment that could severely affect both progress and continuity. There is a lack of consensus among the main European pharmacopoeial traditions, complicated by diverse national regulatory practices, as concerns the quantifying criteria for non-toxic raw materials and stocks from botanical origin. This threatens the continuity of the further integration of homeopathic quality standards into the European Pharmacopoeia.

ECHAMP’s position is clear: the work of EDQM is extremely valuable and the further integration of homeopathic monographs is of paramount importance for quality management, public health and the general development of the industry sector. ECHAMP, its experts and its member companies confirm their wish that the European Pharmacopoeia continues to work on monographs of homeopathic stocks and preparations.

For this reason, ECHAMP experts invested major effort in 2016, with an intensive and critical appraisal of the different European pharmacopoeial traditions. They agreed that a solid bridge needs to be based on rational pharmaceutical analysis. It was generally felt that while an approach which always requires quantification of a substance might bring clarity and equal treatment, it may not take sufficient account of the special characteristics of homeopathic preparations. On the other hand, while an approach which never requires quantification of a non-toxic substance may build on existing practice, it may in several cases lack consistency.

As a result, the experts found that it would not be possible for either approach to bridge the gap for Ph. Eur. Instead, a concept will need to be worked out that builds on the strengths and overcomes the weaknesses of both approaches. It was also felt that the discussion published in Pharmeuropa in 2013 and 2014 does not sufficiently differentiate between arguments for quality, safety and effectiveness. As a first step, we need to take a discerning look at the different arguments and then come to a more solid review of the approach so as to progress the debate.

The ECHAMP expert community is working intensively on a solid pharmaceutical rationale for quality criteria and decision making, including quantification. ECHAMP’s aim is to foster a constructive discussion with the technical committees of the European Pharmacopoeia.

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Endorsing science in our sector

Homeopathy is a much debated topic but few critics are familiar with the essential facts.

The field of scientific research in homeopathy and anthroposophic medicine is dynamic and evolving. Its scientists are passionate, committed to expanding the boundaries of science and motivated to ensure proper integration of these therapies into health care. This is an academic sector increasingly making its voice heard and focused on speaking with one voice. In 2016, ECHAMP worked to give prominence to the work of organisations active in this field.

ECHAMP workshop: Homeopathic and anthroposophic medicinal products in society

On 25 April, ECHAMP hosted an expert workshop in Stockholm to address the status of scientific evidence for these products and therapeutic systems. The workshop was supported by the Swedish Association for Scientific Homeopathy. A high profile panel of sector scientists presented the growing body of high quality clinical evidence and the status of research into the mechanism of action of homeopathy and the status of clinical evidence on the effectiveness of therapeutics with anthroposophic medicinal products.

About 50 ECHAMP delegates were joined by interested stakeholders from Sweden.

Homeopathy – what’s the evidence?

Homeopathy is a much debated topic that attracts regular media attention but few critics are familiar with the facts.

The Homeopathy Research Institute (HRI) website provides in depth, accurate and reliable information to those who want the facts about homeopathy research, providing clear answers to the most commonplace criticisms of homeopathy in the light of current scientific evidence.

With support from ECHAMP in 2016, HRI has now made this material available in French, German, Italian and Spanish.

Accurate and reliable information

Policy and decision makers have a responsibility to follow this debate in depth, to understand the evolving evidence base and the specific quality needs of these products, and to make well-informed decisions based on the most accurate and up-to-date information.

In this, organisations such as HRI, Wissenschaftliche Gesellschaft für Homoöpathie (WissHom) and Groupe International de Recherche sur l’Infinitésimal (GIRI), a group of scientists dedicated to the study of ultra-low dose impulses or very high dilutions, have a significant role to play. They work to meet and establish the highest standards of research and to answer the most prominent questions facing the sector.

The role of industry

A trend towards increasing co-operation with the academic sector can be perceived amongst ECHAMP members, half of whom foster co-operation with universities. Academic topics range from clinical aspects to pharmaceutical development.

In addition, industry continuously undertakes serious work to identify appropriate quality standards that satisfy the specific characteristics of these products. It seeks to establish the retrospective scientific rationale for two hundred years of successful manufacturing and distribution of these products.
Membership Assembly 2016

ECHAMP’s annual Membership Assembly was held in Stockholm on 26 April, chaired by ECHAMP Board member, Sven Backlund of Biosan AB. Members from around the EU came together for two days of meetings, networking and annual formalities.

The Membership Assembly was supported by an expert workshop on homeopathic and anthroposophic medicinal products in society, including a session on the scientific status of these products (see page 7). The second session discussed how regulation is matching demand for these products. It was moderated by ECHAMP President, Dr Gesine Klein, and addressed some specific regulatory challenges for these products in Sweden and elsewhere, as outlined by Dr Mónica Mennet-von Eiff, Member of the Board of ECHAMP and Dr Sandra Holt of the Swedish Medicines Agency. It is hoped that the workshop discussion will help inform the current debate in Sweden about regulation for these products.

In 2017, ECHAMP members will head to Berlin for their Membership Assembly 24-25 April. The chair of the Membership Assembly will be Mathias Hevert, Board member of ECHAMP and Managing Director of Hevert Arzneimittel.

Membership

In April, ECHAMP members voted unanimously in favour of new Swedish Full Member, DCG Nordic AB, a manufacturer of homeopathic medicines with Nordic distribution; it also owns two health stores, one in Gothenburg and one in Stockholm. This brings the total number of Full Members of ECHAMP to 45, from 18 different EU member states.

Information services

ECHAMP continues to make available the highest quality technical and other information about homeopathic and anthroposophic medicinal products through our website, special reports and publications. Our electronic news service, ‘News from ECHAMP,’ provides regular updates on developments affecting the sector. New this year is a quarterly round-up of relevant stories in the news.

In 2016, ECHAMP published two special reports: a review of the adopted HMpWG text – Points to consider on safety of homeopathic medicinal products of biological origin, with an overview of the accepted ECHAMP comments on this consultation; and a summary on the results of HMpWG consultations on First safe dilutions.

ECHAMP also published a two page handout with at-a-glance sales and demand data for our sector.

ECHAMP Full Members receive additional information, reports and services.
ECHAMP, the European Coalition on Homeopathic & 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 these products. It advocates in favour of an appropriate regulatory environment for these products in the EU.