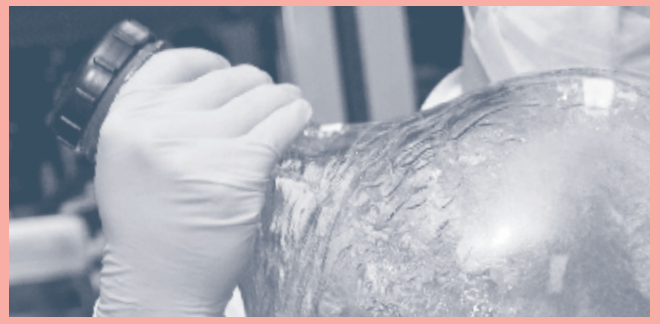
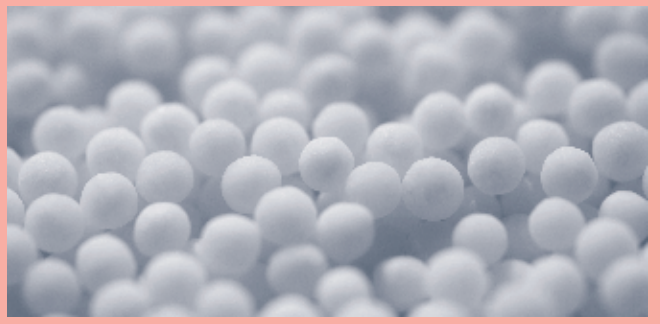
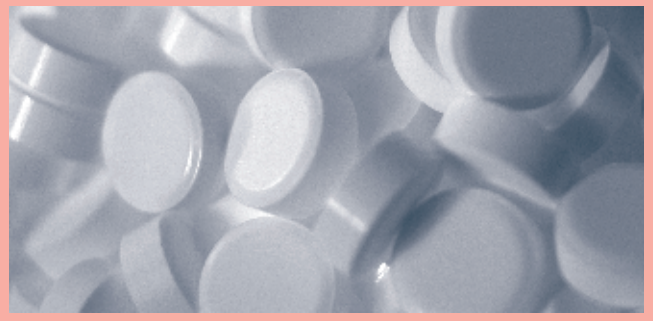






Annual Report 2018

ECHAMP

European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

Contents

Front cover photo: Thomas Neu, Picture provided by Dr. Reckeweg

Words from the President

A strong foundation, determined actors and systematic progress

Step by step, with a stronger common voice, we see progress on important technical issues: we thank all those involved.

The public actors in the field of homeopathic and anthroposophic medicinal products, including the European Commission, the national medicines agencies and the various technical committees and working parties of the European Directorate for the Quality of Medicines & HealthCare and the Heads of Medicines Agencies, have made sincere efforts, rooted in sound European Union legislation, to develop coherent, sustainable quality standards for this sector. We thank them for this work.

Legislation for homeopathic and anthroposophic medicines stems back to the early 1990s and is based on a strong foundation.

On the one hand is the broad use of homeopathic medicinal products in all EU Member States and on the other the EU principles of free trade and freedom of choice.

This annual report presents the successful outcomes of a series of meetings in 2018, in which ECHAMP's renewed efforts to ensure good dialogue and collaboration with key stakeholders in our field resulted in some solid progress on key technical issues for our industry. The sector, mostly supported by the relevant institutions, is intensifying its efforts to find constructive and concrete solutions to shared problems.

Certain actors are apparently determined to undermine this established framework and to derail these efforts.

Some high profile actors base their arguments on false information and unscientific methods. Is populism in science fuelled by personal ideology?

How is it that this comparatively small and emerging sector is able to fill the headlines so regularly?

It is intrinsic to its specific paradigm that homeopathy, since its inception, has always been the subject of scientific debate, and we fully believe this is important. True progress requires the inclusion of homeopathy as a research field for academia. And today, there are ever growing grounds for constructive scientific discussion in this field. It is therefore unacceptable that some high profile actors in this public debate base their arguments on false information and unscientific methods, with the intention of influencing policy making on homeopathic medicinal products.

Two recent international initiatives of apparently well-reputed scientific organisations, the Australian National Health and Medical Research Council (NHMRC) and the European Academies Science Advisory Council (EASAC), have resulted in a link between scientific misinformation and

continued overleaf →

Progress in implementation of EU legislation for homeopathic medicinal products must be protected and further developed.

— Dr Gesine Klein, President, ECHAMP

an assertion of the need to adapt regulation for homeopathic medicinal products. In the latter case, this effort was based not just on incomplete and misleading representation of the scientific basis for these products but also on a visible lack of knowledge of existing regulation. In Australia, an Ombudsman challenge is in progress, requiring NHMRC to answer charges of scientific misconduct, procedural breaches, bias and conflict of interest.

EU regulation for homeopathic medicinal products has a strong foundation.

As the European elections and a new Commission term approach, it is time to emphasise again the deep roots of EU regulation for these medicinal products. The underpinning legislation stems from a dual motivation: on the one hand, the established and high demand by the citizens for these products, and on the other, the principle established under the Treaty of Rome of free movement of goods and the resulting need to guarantee quality and safety. This strong foundation was reconfirmed by the European Commission in 1997 and by the European Parliament in 1998.

Since then, manifold data confirm significant to high demand for homeopathic and anthroposophic medicinal products in at least two thirds of EU Member States, some with and some without a long-term tradition for these products.

Most recently, a 2017 report from the Homeopathic Medicinal Products Working Group of the Heads of Medicines Agencies reconfirms substantial legitimacy for EU regulation in this field. All 24 responding EU Member States except two (Cyprus and Malta) confirm the presence of a market for homeopathic medicinal products and therefore the practice of homeopathy in their countries. Even in Cyprus and Malta, there exist organisations of homeopathic practitioners, indicating the practice of homeopathy in those countries as well. For their part, anthroposophic medicinal products are marketed in 13 of 27 responding states, demonstrating considerable distribution and practice.

Patients and their healthcare providers set the trends in mutual respect and responsibility.

Homeopathic and anthroposophic medicinal products are used in primary and clinical care across Europe. A substantial body of scientific research demonstrates the effectiveness of these forms of treatment; a growing body of published clinical studies confirms their real-world effectiveness — 70% of those that use homeopathy experience improvements in health.

Western medicine is facing the huge challenge of management of non-communicable diseases. These medicines can offer valuable treatment options for health challenges such as mulitmorbidity, poly-pharmacy, chronic diseases and an ageing population. They can contribute to safe and effective strategies to reduce the use of antibiotics. They can, and already do, contribute to the sustainability of health systems.

EU institutions as guardians of a liberal European society: the outlook for our sector

The upcoming European Parliament elections and the next Commission term are casting a shadow across Europe. The institutions are under threat of increasing populism and a widespread loss of trust in governments.

In this context, progress at European level in any area must be protected and further developed. In our sector, the foundations have been laid and the standard-setting process must go on, to allow the European politicians and institutions to:

- continue to respect the collective wish of the European voters for these medicines.
- take note of the increasing body of research data substantiating this sector and to prioritise investment in research on these topics.
- better consider the potential contribution of homeopathic and anthroposophic medicinal products to the big health challenges Europe is facing today.

As ECHAMP continues its work to improve the situation for homeopathic and anthroposophic medicinal products in the EU, we are increasingly determined to build stronger bridges with other stakeholders, with EU and other European and national institutions and with the national medicines agencies.

We look forward to continued collaboration throughout 2019 and hope that, step by step, this stronger common voice will better support our case.

Photo: Hevert Pharmaceuticals

Pharmacopoeia

Significant steps in setting standards for our sector

In order to respond to the quality expectations of its users, any industry sector must come to agreement on meaningful standards as true indicators of what can be called 'good quality.' A sector can only grow in a sustainable way if its quality standards are consistent. Harmonised standards also support the free trade of goods, one of the core aims of the European Union (EU).

Underpinning quality standards in medicine is the European Pharmacopoeia, a collection of legally binding pharmaceutical standards of global relevance. For this reason, ECHAMP concentrates huge efforts to support the work on the European Pharmacopoeia.

The definition of quality standards for homeopathic products addresses two specific questions: firstly, what is the quality of the substances and of the preparations, and secondly, what is the manufacturing method. Together, these questions implicitly address the question as to what is an appropriate quality standard for homeopathic preparations.

In 2018 ECHAMP took some significant steps in the work to elaborate and contribute to standard setting for our sector.

EU convergence: technical workshop on quality control standards

After intense preparation, including thorough expert discussions in several companies over a two year period, ECHAMP organised a symposium on 2nd May in Strasbourg: EU *convergence – Technical Workshop on Quality Control Standards*.

The aim was to involve all concerned companies in Europe in a solution-oriented discussion on the sticking points as regards pharmacopoeial substance monograph standards. In particular, there was no clear common understanding as to how to deal with quality standards for non-toxic homeopathic preparations. Different approaches still blocked the way to a harmonised pharmaceutical standard.

It was therefore urgent and essential to give a clear message to the European Directorate for the Quality of Medicines & HealthCare (EDQM), the 'gold standard' standard-setting agency on pharmaceutical quality, that the sector fully acknowledges and appreciates the effort that has been invested up to now on homeopathic preparations in the European Pharmacopoeia.

ECHAMP acted as coordinator and invited its own forty-one members from 16 EU Member States plus Norway, and industry associations from France, Germany and Switzerland. Twenty-five participants — qualified persons, heads of quality control, regulatory affairs and quality assurance experts — were present, including experts from manufacturing companies from France, Germany and Switzerland, ECHAMP members and non ECHAMP members, as well as representatives of national industry associations. Almost all manufacturing companies with a 'trend setter' function sent their experts, so the participation can be considered as highly representative for the industry producing homeopathic and anthroposophic medicinal products.

> The sector fully appreciates the effort that has been invested up to now on homeopathic preparations in the European Pharmacopoeia.
>
> Michèle Rivasi MEP, Member of the European Parliament's Environment Public Health and Food Safety (ENVI) Committee, opened the meeting with a short, unambiguous statement (*see right*). She expressed the need for industry sectors to converge on and solve technical issues. She also pointed to the growing global dimension of complementary medicine, of which homeopathy and anthroposophic medicine are part.

Strasbourg, May 2018: Leading quality experts join the technical workshop on quality control standards.

> Participants were unanimous in their agreement that EDQM should continue its work on homeopathic preparations.

The participants exchanged views on several technical presentations and then came to agreement on some basic conclusions.

Firstly they were unanimous in their agreement that EDQM should continue its work to implement homeopathic monographs into the European Pharmacopoeia to ensure harmonised standards on quality and safety for public health in Europe.

Secondly they underlined that, for obvious reasons of safety, the higher limit of toxic substances must always be determined.

Given this very basic point, the companies generally agreed that there is a need to work on specific quality aspects for homeopathic preparations, implementing current scientific state of the art approaches and methods. The standards should be appropriate for complex, process-defined substance units such as homeopathic preparations from natural origin. It is easy to underestimate this statement, but it describes the specific profile of homeopathic preparations emphasising two distinct aspects — on the one hand the manufacturing process itself, and on the other the resulting holistic entity, the quality of which must be assessed as a whole, rather than by identifying single molecules in a more or less arbitrary way.

This major milestone itself opens up another significant question in the implementation of quality standards: if the required quality checks are fully implemented at each step of the production chain, from the very beginning (e.g. cultivation, harvesting etc.), then what further checks are still essential in the final product?

For medicinal products defined by their manufacturing process, constructive discussion around this question can achieve two aims: continuous increase of the good quality of homeopathic and anthroposophic medicinal products and better, more sustainable regulation. Step by step, ECHAMP will elaborate the concepts and offer them for discussion by the experts concerned.

For non-toxic preparations, semi-quantitative methods should be specified and further developed for those compounds which are essential to the quality of the product. A key discussion point relates to the option of including high precision thin layer chromatography (HPTLC). HPTLC is an enhanced form of thin-layer chromatography that achieves a higher resolution and thus allows more accurate quantitative assessments.

The conclusion of the workshop was communicated to EDQM. In June, as a result of a meeting between EDQM and the decision makers in the national agencies, EDQM took the decision to continue its work on quality standards of homeopathic preparations.

ECHAMP very much welcomes this decision.

We need a performing homeopathic industry.

I believe in complementary medicine and integrative medicine. That is why we need convergence of the actors.

Your institutions have a role to play in the harmonisation of norms and rules within the EU and worldwide.

If we look at the general situation at a global scale, what do we see?

New players from China and India are promoting their own complementary medicines, preparing themselves to access new markets. Homeopathy is a European tradition and we should stop losing time. The world is moving on. And homeopathy, while hesitating, is exposing itself to a danger.

That is why I wish you, who are meeting in Strasbourg, to find solutions to questions which seem unsolvable, especially on the issues concerning the European Pharmacopoeia.

The homeopathic sector has its place in European health care. Let us think five years ahead and roll up our sleeves; let us be as innovative and inclusive as the medicine you are defending, which is developing itself for the good of everyone.

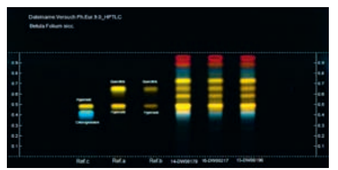
Michèle Rivasi MEP, Strasbourg, 2 May 2018

Translation by ECHAMP

I wish you to find solutions to questions which seem unsolvable, especially on the issues concerning the European Pharmacopoeia.

— Michèle Rivasi MEP

High-performance thin-layer chromatography



Regulatory environment

Building on a strong foundation

Homeopathic Medicinal Products Working Group

It is the role of the Homeopathic Medicinal Products Working Group (HMPWG), set up under the auspices of the Heads of Medicines Agencies (HMA) and composed of representatives from the national competent authorities (medicines agencies) of the EU Member States, to improve the regulatory environment for homeopathic and anthroposophic medical products in the EU.

This forum provides guidance on the assessment and registration of homeopathic medicinal products for the authorities and for applicants. Its members work at both national and European level; they therefore have daily experience of the major challenges the sector faces in finding and setting common standards.

The HMPWG 2017 report, *The Regulatory Status of Homeopathic Medicinal Products*, confirms substantial legitimacy for EU regulation in this field (see *Words from the President, page 1*) and therefore a strong foundation for the work of this group.

Activities 2018

In 2018, HMPWG continued its work on a number of topics — list of first safe dilutions, lists of stocks for which homeopathic use is justified, safety of nosodes and question and answer documents on quality.

ECHAMP continued to support the efforts of this group in 2018 by submitting comments to HMPWG on four consultations. The detailed work from experts in our member companies contributes an essential ingredient to the work, helping the authorities understand the real experience of our sector and the considerable investment the companies make to meet the defined standards.

However, there are many instances in which industry experience is not taken into account and ECHAMP and its members continue to have the following concerns:

- *first safe dilutions*: some HMPWG calculations result in high first safe dilutions without acceptable justification.
- *consolidated lists of stocks* for which homeopathic use is justified: to date only stocks from official pharmacopoeias are included; they exclude any non-pharmacopoeial, therapy-specific stocks; there has as yet been no indication that these will be included in the future.
- *work on quality*: Generally, the HMPWG question and answer document on quality topics is a helpful tool. ECHAMP hopes that this helps to keep the common technical document dossiers for homeopathic and anthroposophic medicinal products on a reasonable level as foreseen in the superordinate pharmaceutical legislation, that is to differentiate between data needed for the registration dossier and data already covered by Good Manufacturing Practice (GMP). ECHAMP is following up and commenting on these papers.

Austrian Presidency: Meeting in Vienna

On 17 October, HMPWG invited the industry to a dialogue meeting. The meeting was organised by the Austrian medicines agency (AGES) during the Austrian Presidency of the EU. Representatives of three European associations were present: ECHAMP, AESGP (Association of the European Self-Medication Industry) and EUCOPE (European Confederation of Pharmaceutical Entrepreneurs).

The positions presented reflected the alignment between the three industry organisations.

ECHAMP regulatory experts presented three issues faced by the industry:

- *Quality – Flexibility of suppliers of raw materials*: it should be possible to change the raw material supplier for a homeopathic starting material without prior approval by the agency in order to be able to react, for example in case of crop failure.
- *Quality – Determination of re-test dates of intermediate dilutions*: the transfer of the expiry date and/or stability data of stocks or lower potencies to intermediate potencies is an option if no individual stability data are available. This should be a requirement for GMP, not a requirement of the registration dossier.
- *Safety – First safe dilution calculations*: the evaluation criteria for homeopathic medicinal products should stem from a transparent and comprehensible assessment of scientific literature data. They should be the same as for other medicinal products, using as the reference basis for product-specific calculations the acceptable amount (concentration) rather than the first safe dilution expressed as a potency; where appropriate, special warnings could be included on the label of Art. 14 products (for example, particular groups of patients, maximum daily intake and duration of use). The current HMPWG decision tree in the Points to Consider on the calculation of first safe dilution should be amended to include the Cramer scheme.

The positions presented reflected the alignment between the three industry organisations. It was followed by an open discussion with the regulators on potential solutions. The participants also discussed their expectations for the future.

ECHAMP hopes that it will be possible to hold this kind of dialogue meeting with the agencies' representatives on a regular basis, maybe once a year; we are prepared to support this in any way we can.

European Medicines Agency

In addition to the detailed technical work with HMPWG, ECHAMP also remains in close contact with the European Medicines Agency (EMA), the regulatory body set up for the evaluation and supervision of medicines in the EU, including centralised pre- and post-authorisation procedures, including pharmacovigilance. In 2018, ECHAMP reacted to a number of EMA initiatives which had a direct impact on our sector.

Pharmacovigilance requirements

In 2018, changes in pharmacovigilance obligations resulted in inconsistent and questionable requirements for manufacturers of homeopathic medicinal products. According to Article 16(3) of EU Directive 2001/83/EC, homeopathic medicinal products registered under the special, simplified registration procedure (Article 14) are exempt from pharmacovigilance requirements; there are no EU reporting obligations for suspected adverse reactions for these products. Certain obligations do exist in some Member States, based on national rules.

In 2018, this legal basis was challenged by the full implementation of EudraVigilance, the EMA's centralised European database of suspected adverse reactions to medicines. As a result, new processes have been introduced in some Member States requiring licence holders to submit data for registered homeopathic medicinal products.

Companies are challenged by contradictory requirements at EU and national level. ECHAMP has called on the European Medicines Agency and the Member States to find a more pragmatic solution.

International standards

In 2018, ECHAMP's work contributed to the definition of international standards for the identification of medicinal products in EU based on substance, product, organisation and referential data (EU IDMP/SPOR Task Force).

Fee system review

In July, EMA undertook an in-depth evaluation of its current fee system. In its response to the consultation, ECHAMP highlighted some issues particular to our industry, demonstrating that the current fee system lacks flexibility and the flat-rate fees charged are disproportionate to the requirements of this sector.

It is hoped that this review will lead to the introduction of measures specific to our sector.

The HMPWG 2017 report confirms substantial legitimacy for EU regulation in this field.

ECHAMP is committed to building a regular and consistent dialogue with HMPWG.

Our sector

The homeopathy debate

Homeopathy has always provoked scientific disputes — from its inception, it has been the subject of public debate. This is an intrinsic outcome of its specific paradigms. Scientific debate is important. The actors in the sector are mostly used to this phenomenon, and since the 1990s, there have been ever growing grounds for constructive scientific discussion in this field. Moving forward, true progress requires the inclusion of homeopathy as a research field for academia.

At the same time, however, it is increasingly clear that some actors in this debate base their arguments on false information and unscientific methods, with an increasing intention of influencing policy making on homeopathic medicinal products.

Two recent high profile international initiatives of apparently well-reputed scientific organisations, the Australian National Health and Medical Research Council (NHMRC) and the European Academies Science Advisory Council (EASAC), have resulted in a link between scientific misinformation and an assertion of the need to adapt regulation for homeopathic medicinal products. In the latter case, this effort was based not just on incomplete and misleading representation of the scientific basis for these products but also on a clear lack of knowledge of existing regulation. In Australia, an Ombudsman challenge is in progress, requiring NHMRC to answer charges of scientific misconduct, procedural breaches, bias and conflict of interest. In both cases widespread misreporting in the media is damaging the sector.

In 2018, the global homeopathic community united in its efforts to bring pressure on NHMRC to correct the mistake it made when it published an inaccurate and scientifically unreliable report on homeopathy.

Dialogue and collaboration

Step by step, a stronger common voice will better support our case.

Diverse interests in this sector share the common goal of improving availability of and accessibility to homeopathic and anthroposophic medicinal products and their related therapies. Each stakeholder has its own perspective, but we have far more in common than that which divides us. In 2018, ECHAMP played a pivotal role in bringing diverse parties together to find constructive joint solutions for the range of problems faced by the sector and the industry.

As we continue to work to improve the situation for homeopathic and anthroposophic medicinal products in the EU, ECHAMP is increasingly determined to build stronger bridges with other stakeholders, with EU and other European and national institutions and with the national medicines agencies.

ECHAMP workshop:
The case of antimicrobial resistance

ECHAMP's collaboration with other stakeholders was further reinforced at our annual Membership Assembly in April in Marseille. The workshop *Contribution of Homeopathy to Society and Patients: the case of antimicrobial resistance* brought together public health players with doctors, scientists and patients to consider the positive contribution complementary medicine, in particular homeopathy and anthroposophic medicine, can make to the growing public health threat of antimicrobial resistance. ECHAMP member companies were joined at the workshop by French stakeholders to consider how to address this threat in an integrated and co-ordinated way.

ECHAMP workshop: *The case of antimicrobial resistance*, Marseille, April 2018

Some actors in this debate base their arguments on false information and unscientific methods.

Inside ECHAMP

Dialogue and collaboration

Membership Assembly 2018

In 2018, ECHAMP's annual Membership Assembly was held in Marseille, France, welcoming Full Members from across Europe. With stunning views from high above the port of Marseille, members enjoyed two days of discussion and networking. The Membership Assembly was chaired by Christopher Wise, chief executive of ECHAMP member, Sevene Pharma.

ECHAMP was pleased to welcome its first extra-ordinary partner, the company Schmidt Nagel from Switzerland. This is a new category of membership for companies located within Europe but outside the EU or EEA. Schmidt Nagel, founded in 1927, develops and distributes both single and complex homeopathic products in Switzerland, and is fully committed to the highest quality of manufacture of its products. ECHAMP looks forward to close collaboration with this new partner.

During the two days, members also took part in an expert workshop, *Contribution of Homeopathy to Society and Patients: the case of antimicrobial resistance* (see *page 9*).

The 2019 annual Membership Assembly will be held in Dublin, Ireland from 8-9 April and chaired by Martin Murray, Chairman of the Board of Irish member company, New Vistas Healthcare.

Support for members

The close community of ECHAMP members includes companies active in the production and distribution of homeopathic and anthroposophic medicinal products in Europe. They come together to develop the industry sector and the market for both self-medication and prescription medicines. ECHAMP works to advocate and support standards and requirements, including effectiveness, in line with the tradition and therapeutic systems of homeopathy and anthroposophic medicine as practised in Europe. A major focus is to advocate an appropriate and well-balanced EU regulatory environment that reflects and ensures the specific quality and high safety of these products and to establish the industry as a credible and reliable health player at EU level.

In 2018, members contributed their expertise in some high profile workshops, including the Pharmacopoeia workshop in Strasbourg in May (see *page 4*) and the HMPWG dialogue meeting in Vienna in October (see *page 6*). In both cases, ECHAMP helped to facilitate wider industry collaboration on these topics critical to all players in the sector.

ECHAMP members continue to receive *News from ECHAMP*, providing regular information about developments and a roundup of media coverage in our sector. In 2018, they had access to privileged sector and market information and specialist input and advice for specific market situations. They receive monthly briefings on the association's activities and access to specialist information on the website.

Experts from ECHAMP member organisations gave technical input into four different consultations for the Homeopathic Medicinal Products Working Group and one by the European Medicines Agency. We thank them for their efforts.

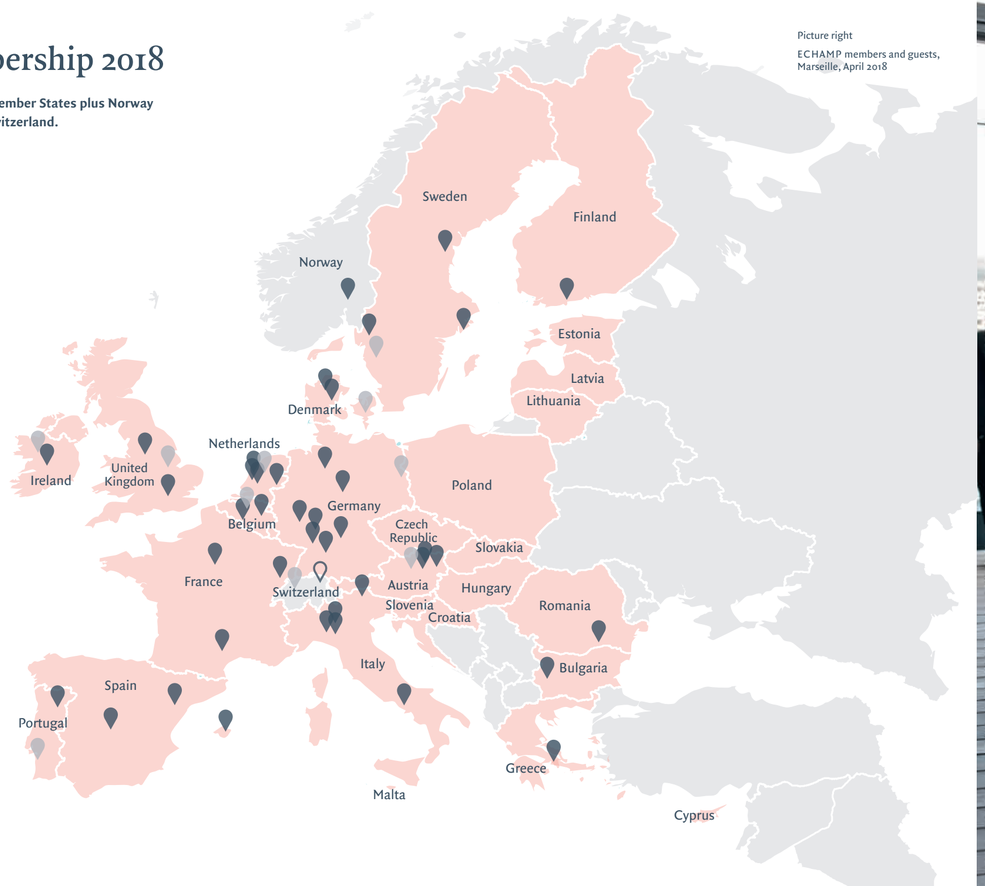
ECHAMP Membership Assembly, Marseille, April 2018

ECHAMP helps to facilitate a wider industry collaboration critical to all players in the sector.

ECHAMP membership 2018

41 Full Members from 16 different EU Member States plus Norway and one Extraordinary Member from Switzerland.

- **Full Member of ECHAMP**
- **Associated Partner of ECHAMP**
- **Extraordinary Member of ECHAMP**



Picture right

ECHAMP members and guests, Marseille, April 2018

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.

ECHAMP E.E.I.G.
Rue Washington 40
B-1050 Brussels
T +32 2 649 94 40
E office@echamp.eu
www.echamp.eu

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