ECHAMP

European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

Annual Report 2019

Support our industry in standing up for patient

CHOICE

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Words from the President

The industry for homeopathic and anthroposophic medicines: Standing up for patient choice

"We seek stronger support from politicians and policy makers to facilitate an open and objective discussion on the benefits and potential of these medicines."

David Reckeweg-Lecompte, President, ECHAMP

A changing political landscape

In 2019, the European electorate sent some clear messages to their politicians and policy makers, putting pressure on the EU institutions to redefine their role in the face of a surge of concern for the environment. The new Commission has confirmed its commitment to implementing the UN goals for sustainable development and has given priority to supporting the Member States in improving the quality and sustainability of their health systems.

This sets a welcome context for our industry, which can make a valuable contribution towards meeting these goals.

An established, patient-led, sustainable industry

The European industry for homeopathic and anthroposophic medicines has been serving patients now for over 200 years. The industry is, largely, defined by the demand from prescribers and patients for a wide range of products, providing millions of EU citizens with their choice in healthcare. These medicines can be individually prescribed by a doctor or practitioner or selected for self-medication for everyday ailments. Companies offer a broad spectrum of products for individual patients, and the industry is characterised by huge variety, with thousands of different starting materials, potencies and dosage forms required for the proper practice of the therapies. Despite the broad spectrum of products, its medicines have a negligible environmental impact.

A long-standing and strong foundation in European law

The EU institutions have succeeded in creating a system that allows patients the option of accessing safe, high quality homeopathic and anthroposophic medicinal products of their choice.

This sector has a strong foundation in EU legislation *(see page 4)*, first established in 1992 to ensure free trade within the European Union and freedom of choice for patients while safeguarding quality and safety. Today, the industry is highly regulated and the European system ensures the same high standards for quality and safety for these as for all medicinal products.

In 2017, a report by the Homeopathic Medicinal Products Working Group of the Heads of Medicines Agencies substantiated the 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.

Europe leads the way in a global context

The European industry continues to lead the way globally with its expertise in the manufacture of homeopathic and anthroposophic medicinal products.

The 2019 World Health Organisation *Global Report on Traditional and Complementary Medicine (see page 10)* confirms the use of homeopathy in 100 countries around the world. In his foreword, WHO Director General, Dr Tedros Adhanom Ghebreyesus, describes traditional and complementary medicine as an "...important and often underestimated health resource ... to help tackle the unique health challenges of the 21st century." In many countries, such as India, Mexico, Switzerland, Germany and Luxembourg, the government's commitment to these therapies is clear and strong *(see page 11)*.

The European Commission itself recognises the importance of ensuring patient choice in this sector,

The millions of users of homeopathy and anthroposophic medicine do so because they experience real improvements to their health.

saying that "The current regulatory framework for homeopathic products … strikes a balance between ensuring their quality and safety … while at the same time giving citizens access to these products."

Nevertheless, in countries such as France, Spain, UK and Australia, attacks on this sector are resulting in government restrictions on patient access to these medicines. Such moves fly in the face of patient preferences and are out of step with the global trend (*see page 10*).

We should be proud of the European heritage and global standing of this sector and work to protect its future.

Standing up for patient choice

The millions of users of homeopathy and anthroposophic medicine do so because they experience real improvements to their health (*see page 9*). They are convinced of the benefits, have confidence in the high safety profile of these medicines and express a high level of satisfaction with these treatments.

Homeopathic and anthroposophic medicinal products, currently used in primary and clinical care across Europe, have an important role to play in the face of major health challenges in the EU. They offer valuable treatment options for health challenges such as multimorbidity, polypharmacy, antimicrobial resistance, chronic and non-communicable diseases and an ageing population. A substantial body of scientific research demonstrates the effectiveness of these forms of treatment; a growing body of published observational studies confirms their real-world effectiveness. They can contribute to the sustainability of health systems by significantly reducing treatment costs. In this context, it is important to ask why, in Europe, is pluralism in health care not being encouraged?

EU citizens have the fundamental right to access balanced and neutral information to enable them to choose the health care most suited to their needs. In the changing global context, the European political and regulatory conversation risks losing sight of the long-established contribution that homeopathy and anthroposophic medicine make to the health challenges of our times and the social and economic benefits of these therapies. The European industry and the wider sector are determined to communicate the lasting relevance and value of these medicines. We are committed to strive for greater integration of these therapies into health care.

Looking forward

As ECHAMP moves into 2020 with a new management team, the ECHAMP Board of Management warmly thanks former President, Dr Gesine Klein and General Secretary, Christiaan Mol for their dedication and achievements during their terms of office. We continue to build on this hard work to secure and improve the situation for homeopathic and anthroposophic medicinal products in the EU.

All parties share responsibility for this work – whether industry, regulator, health professional, policy maker or politician. At ECHAMP, we seek stronger commitment at European and at national level, to facilitate an open and objective discussion on the benefits and potential of these medicines. It is time for politicians and policy makers to recognise and acknowledge the patients' preference and to support our industry in standing up for the people's choice for these medicines.

David Reckeweg-Lecompte took over from Dr Gesine Klein as President of ECHAMP in June 2019.

Photo:

ECHAMP Board of Management, October 2019

The Board of Management is committed to securing and improving the situation for homeopathic and anthroposophic medicinal products in the EU.

A well-regulated sector, an established European industry

An established European industry

This long-standing European industry has a strong foundation in EU law and has been serving patients now for over 200 years. Legislation for homeopathic medicinal products was first established in 1992 (*see inset*) with the aim of ensuring free trade within the European Union and freedom of choice for patients while safeguarding quality and safety. Today, manufacturers in Europe work to the same high quality and safety standards for these as for all medicinal products and there are more than 12,000 registered homeopathic medicinal products in the EU Member States and more than 3,000 homeopathic medicinal products with a marketing authorisation.

The EU institutions have succeeded in creating a system that allows the millions of users of these products the option of accessing safe, high quality medicinal products of their choice. However, the implementation of the current legislative framework is still not fully complete in all Member States[1], which has led to a lack of uniform availability of the products.

An increasingly complex regulatory environment

ECHAMP works hard to ensure that the specific characteristics of homeopathic and anthroposophic medicinal products are taken into account in an appropriate way when it comes to new guidelines for our sector, in particular from the European Medicines Agency (EMA) or the Heads of Medicines Agencies (HMA).

Although in principal the legislator foresaw reasonable approaches for these products (*see inset*), the actual experience is that the regulatory burden for the sector is increasing from year to year regarding administrative workload and technical dossier requirements.

[1] Study on the Availability of Medicinal Products for Human Use, Matrix Insight, 2012

A quick history of regulation of our sector

In 1992, the Council of the European Communities stated in the preamble to Directive 92/73/EEC that homeopathy was prescribed and used in all Member States. It directed the Member States to implement certain changes in their national legislation to harmonise the market of homeopathic products. In 2001, Directive 92/73/EEC was replaced by Directive 2001/83/EC on the Community code relating to medicinal products for human use. The intention was to:

- Create a legal framework that would allow patients access to the medicinal products of their choice provided that all precautions were taken to ensure the quality and safety.
- Provide users of these medicinal products with a clear indication of their homeopathic character and sufficient guarantees of quality and safety
- Harmonize the rules relating to the manufacture, control and inspection
- Permit the circulation throughout the Community of medicinal products which are safe and of good quality.

It resulted in a special simplified registration procedure for homeopathic medicinal products without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient.

In addition, the standard rules apply to the authorisation of homeopathic medicinal products with indication. However, the legislation allows Member States to introduce or retain in their territory specific rules for the preclinical tests and clinical trials of these products. This means they have the option to recognise the specific characteristics of homeopathic medicinal products.

2019 activities – quality and safety

Over a period of time, ECHAMP has given input to diverse draft Question and Answer documents on quality from the Homeopathic Medicinal Products Working Group of the Heads of Medicines Agencies (HMPWG) of the HMA. In 2019, we were reassured to see that some of our comments have been accepted by HMPWG, who have adopted final versions of the Question and Answers documents on the quality of homeopathic medicinal products. The direct dialogue with HMPWG in 2018 was very helpful to foster a shared understanding of the daily practice of the manufacturing of homeopathic and anthroposophic medicinal products and its presentation in the product dossiers.

However, on the topic of safety assessment of homeopathic and anthroposophic medicinal products, the discrepancies regarding the calculation of first safe dilutions between industry and the agencies persist. This particularly affects those products which are on the market in potencies between mother tincture and D8. ECHAMP maintains the position that the evaluation criteria should be based on transparent assessments of scientific literature data as applied for conventional medicinal products.

Increasing workload and rising fees

In common with the whole pharmaceutical sector, our industry is suffering from the increasing workload and rising fees for the lifecycle management of our existing products. This burden is all the more severe for our sector, where a huge number of products are needed to keep these therapies available for patients. The workload and heavy cost have the effect of preventing companies from investing in the development of new products or modern administration forms.

We continue to recognise and appreciate the work of HMPWG and the effort it invests in this sector. We hope that it will continue to invest resources into the work on appropriate implementation of regulation for homeopathic and anthroposophic medicinal products and to seek further opportunities to enter into dialogue with the industry.

The direct dialogue with HMPWG in 2018 was very helpful to foster a shared understanding of the daily practice of the manufacturing of homeopathic and anthroposophic medicinal products.

Pharmacovigilance

Identification of medicinal products

The European Medicines Agency (EMA) is currently in the process of implementing the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP). This is done in a phased programme based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (SPOR). It is highly important for ECHAMP that the standards for processing data on the medicinal products include – where relevant – a harmonised nomenclature which is suitable to homeopathic medicinal products.

ECHAMP has an observer status in this project and also participates in the EMA task force meetings. Due to the relocation of EMA from London to Amsterdam, task force activities in 2019 were limited. The final version of the EU Implementation Guide for IDMP/SPOR, the draft of which was extensively commented by ECHAMP, is expected in the first quarter of 2020.

Pharmacovigilance requirements: inconsistent and irregular

The EMA is also responsible for the coordination of the EU pharmacovigilance system. In 2018, it was already becoming apparent that changes in the pharmacovigilance obligations for manufacturers of homeopathic medicinal products in the EU were resulting in inconsistent and irregular requirements. In 2019, the situation remained unchanged. The following examples illustrate this.

EMA databases: Of concern to ECHAMP members is the usability of the EudraVigilance Data Analysis System (EVDAS), the central tool for finding and receiving individual case safety reports from the competent authorities, for medicinal product data and for identifying patterns that suggest new safety information. It does not lend itself well to the complexity of our industry where we need to distinguish between multiple similar products, for example, 'Echinacea angustifolia', 'Echinacea purpurea', '…extract' and others, to specify the exact grade of dilution or to differentiate between plants, plant extracts or drug to solvent relation. The process quickly becomes too complicated for those, such as our sector, with high numbers of variables to research. The EudraVigilance web reporting application (EVWEB) can be used as an alternative but is also too complicated when dealing with high numbers of cases.

Special requirements in some Member States: Article 16(3) of EU Directive 2001/83/EC confirms that homeopathic medicinal products registered under the special simplified registration procedure (Article 14) (*see page 4*) are exempt from pharmacovigilance requirements. According to this legislation, there are no EU reporting obligations for suspected adverse reactions for these registered products. In some Member States, certain obligations continue to exist based on national rules.

It is highly important for ECHAMP that the standards for processing data on the medicinal products include – where relevant – a harmonised nomenclature which is suitable to homeopathic medicinal products.

Pharmacopoeia: towards a common quality standard

European health policy aims to strengthen cooperation between Member States in order to improve access to medicines. On the one hand, the pharmaceutical system is related to European policy and on the other hand, it is related to national laws. To promote availability and access to medicinal products, a first step is to ensure harmonised standards of quality and safety.

The European Directorate for the Quality of Medicines (EDQM) enables the development, supports the implementation, and monitors the application of quality standards which allow safe use of medicinal products. These are also seen as a scientific reference in the rest of the world. It is therefore crucial for homeopathic and anthroposophic medicinal products to set quality standards for inclusion in the European Pharmacopoeia.

EDQM has been working hard for many years on the transcription to the European Pharmacopoeia of the homeopathic manufacturing methods and the substance monographs from the German Homeopathic Pharmacopoeia and the French Pharmacopoeia referring to homeopathic manufacturing methods and substance monographs. The work has been fruitful and common standards have been agreed.

A new pilot project

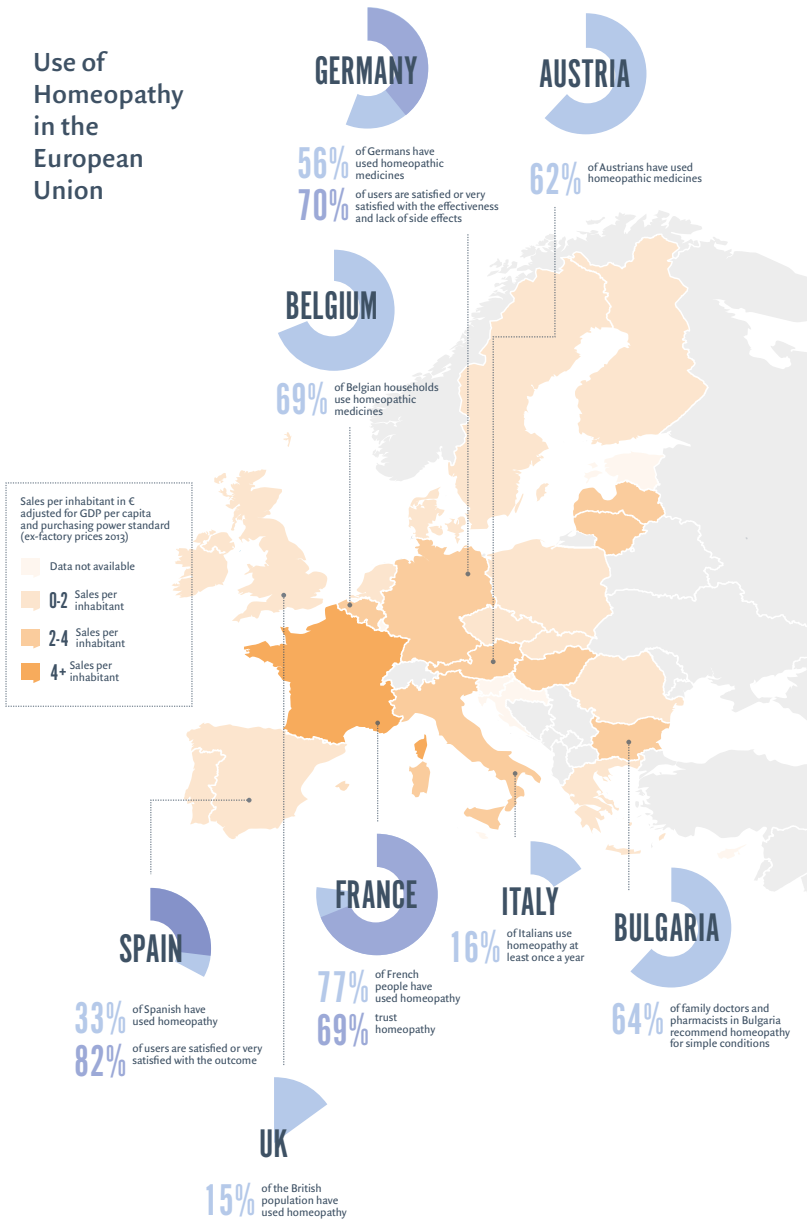
An important step forward was made in 2019. After long discussions on the substance monograph work concerning the standard of an assay in each monograph, and following the example of colleagues of the traditional Chinese medicine group, a pilot project has been set up. The Homoeopathic Working Party, which elaborates monographs on the substances used in homeopathic preparations, is working on three pilot monographs: Calendula, Planta tota, Chamomilla, Planta tota, and Arnica, Planta tota. The aim is to develop a semi-quantitative high-performance thin layer chromatography (HPTLC) as a test. HPTLC is an enhanced form of thin-layer chromatography that achieves a higher resolution and thus allows more accurate qualitative and quantitative assessments.

Once agreement has been reached on that, a robust identity and quality test will have been developed and also a test which allows to measure and monitor stability for important quality markers that can be measured in relation to reference substances added in the HPTLC.

The homeopathic medicines industry is very conscious that agreeing on a common quality standard will further strengthen the strong legal basis homeopathic medicines have in the EU.

It is crucial for homeopathic and anthroposophic medicinal products to set quality standards for inclusion in the European Pharmacopoeia.

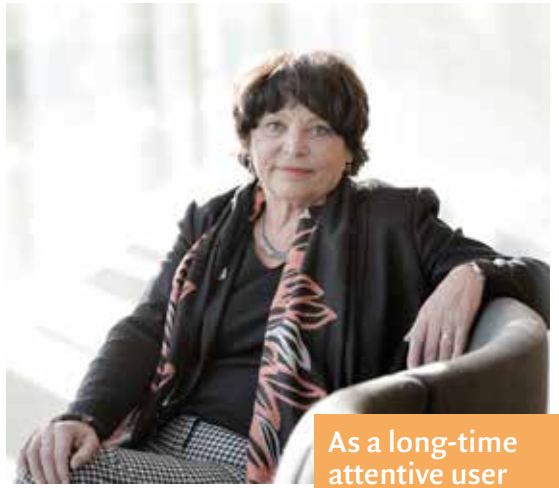
Spotlight on an industry



ECHAMP's new report, *Homeopathic and Anthroposophic Medicinal Products in the EU – Spotlight on an Industry* presents a comprehensive review of the sector, confirming high levels of awareness of homeopathy and anthroposophic medicine in many countries in Europe, with growing use of and demand for these medicines and positive attitudes of citizens towards these therapies.

The publication provides a unique and up-to-date profile of the sector for homeopathic and anthroposophic medicinal products in the EU, outlining the demand for these medicinal products, presenting the characteristics of this industry and summarising the evidence base that underpins their use in health care. It is the only such source for summarised EU data on this sector and includes the results of detailed research with ECHAMP members over a period of time.

In her foreword to the report, Michèle Rivasi MEP welcomes it as "an authoritative source of information." She confirms her commitment to this sector, saying, "Legislation for homeopathic medicinal products has deep roots in their broad use in the Member States. As a long-time attentive user and observer of homeopathic medicines, I have direct personal experience of the important role these therapies play within complementary and integrative medicine. I am committed to ensuring that they take their rightful place within European health care."



As a long-time attentive user and observer of homeopathic medicines, I have direct personal experience of the important role these therapies play within complementary and integrative medicine.

Michèle Rivasi, Member of the European Parliament

ECHAMP's report confirms positive attitude and high demand for homeopathic and anthroposophic medicines.

The global debate

Traditional and complementary medicine is an important and often underestimated health resource.

WHO Director General, Dr Tedros Adhanom Ghebreyesus

The debate around homeopathy and complementary and integrative medicine continues in both a European and a global context.

In 2019, a new report from the World Health Organisation confirms the growth and importance of traditional medicine, including homeopathy. Major scientific and regulatory events, organised by Homeopathy Research Institute and World Integrative Medicine Forum respectively, cast a global spotlight on the sector.

World Health Organisation — new report on traditional and complementary medicine

A new report from the World Health Organisation, the *Global Report on Traditional and Complementary Medicine 2019*, charts the growth of traditional and complementary medicine (T&CM) over the past twenty years, confirming that homeopathy is the third most popular specific complementary medicine after acupuncture and herbal medicine, used in 100 countries around the world.

In his foreword to the report, WHO Director General, Dr Tedros Adhanom Ghebreyesus, calls on policy-makers, health professionals and the public to capitalise on the potential contribution of traditional and complementary medicine to "help tackle the unique health challenges of the 21st century", saying that is "…an important and often underestimated health resource… especially in the prevention and management of lifestyle-related chronic diseases, and in meeting the health needs of ageing populations." He argues that at a time when "consumer expectations for care are rising, costs are soaring, and most budgets are either stagnant or being reduced", traditional medicine should be an option "offered by a well-functioning, people-centered health system that balances curative services with preventive care."

Homeopathy Research Institute tenth anniversary

In June, David Reckeweg-Lecompte, President of ECHAMP, was pleased to attend, along with other members of the ECHAMP Board, the 10th Anniversary celebrations and 4th International Research Conference of Homeopathy Research Institute. Held in London, this was HRI's biggest and most international conference to date. 352 attendees from 38 countries enjoyed a fast-paced programme as 75 researchers and medics presented the very latest research in the field of homeopathy from 27 countries. In line with the 'cutting edge' theme of the conference, key topics included clinical research, fundamental research, qualitative research, lab-based studies and veterinary research. The event will be remembered for the highest quality scientific programme and as the biggest event in homeopathy research to date.

HRI London 2019 – 10 Years of HRI

Advancing global collaboration on regulation

In January, ECHAMP helped sponsor the second World Integrated Medicine Forum in Goa, India, on the regulation of homoeopathic medicinal products. The theme was 'Advancing Global Collaboration' and the event was organised by the Central Council for Research in Homeopathy, with the support of the Indian Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). It was opened in person by Shri Sripad Yesso Naik, Honourable Minister of State for the Ministry of AYUSH. Participants included representatives from World Health Organisation (WHO) and medicines agencies, pharmacopoeia experts, and industry representatives from India and around the world.

Despite the growing demand for homeopathic medicines globally, standards for the regulation of these medicines are highly disparate between different countries and this directly affects their availability. There is an opportunity for the EU, with its expertise in the manufacture and regulation of homeopathic medicines, to endorse its responsibility as global leader in this field and play a role in ensuring safety and security for this growing demand.

Christiaan Mol, then General Secretary of ECHAMP, gave a strategic perspective on how to advance international collaboration in this field, presenting different scenarios based on lessons learnt to date.

The sector fights back

In many countries, the government's commitment to homeopathy and anthroposophic medicine is clear and strong – for example, the investment in the sector is manifest in India; the Mexican Senate has adopted new legislation regulating homeopathic medicine within the context of its new national health service; in the Swiss healthcare system, homeopathy is on an equal footing with conventional medicine and the German and Luxembourg governments have both recently confirmed their commitment to upholding access to homeopathy. However, in other countries, it is becoming apparent that attacks on the sector by opponents of homeopathy are resulting in initiatives by governments that restrict patient access to these medicines, for example the French government's decision to stop funding the reimbursement of homeopathic medicinal products, the Spanish government's national plan against what they call 'pseudotherapies' and the decision in June 2018 by National Health Service (NHS) England to stop funding homeopathic medicines.

In 2019, patients and prescribers were more vocal than ever before, standing up for their right to use the medicines of their choice. More than 1.3 million people in France have signed a petition in favour of upholding the reimbursement of homeopathic medicines; in response to intense and global public pressure to put the record straight, Australia's leading research institute, the National Health and Medical Research Council (NHMRC) publicly confirmed and clarified that 'Contrary to some claims, the [2015 Information Paper on homeopathy] did not conclude that homeopathy was ineffective.'

In 2019, patients and prescribers were more vocal than ever before.

David Reckeweg-Lecompte, President of ECHAMP, meets Shri Sripad Yesso Naik, Honourable Minister of State for the Ministry of AYUSH.

Inside ECHAMP

ECHAMP
Membership Assembly, Dublin 2019

Membership Assembly

In April, ECHAMP hosted a lively workshop for chief and senior executives of the EU industry for homeopathic and anthroposophic medicinal products in Dublin, as part of its annual Membership Assembly activities. Representatives from 26 companies across the EU and EFTA and representatives of some industry associations joined intensive strategic discussions aimed at helping frame the future of the sector. The Membership Assembly itself was chaired by Martin Murray of New Vistas Healthcare. In recognition of his many years of involvement, Martin was appointed as Honorary Member of ECHAMP.

New President, new management

In April, the Board of management of ECHAMP unanimously elected David Reckeweg-Lecompte to be its new President, taking over from Dr Gesine Klein, ECHAMP's President since 2013. Christiaan Mol, General Secretary for the same period, also came to the end of his term. Both Gesine and Christiaan remain active in the association, ensuring a smooth transition to the new management and the continuity of certain projects.

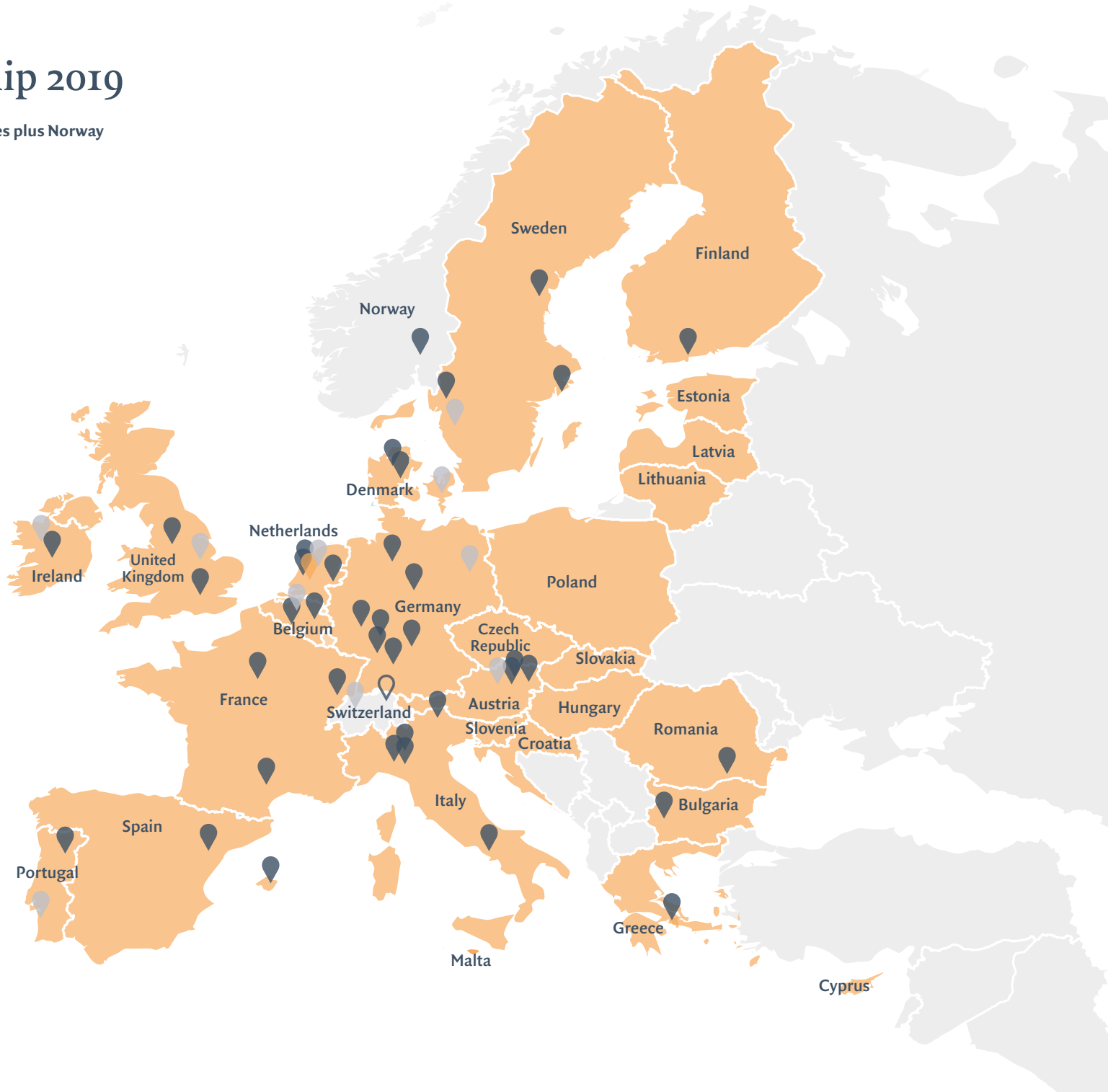
As ECHAMP moves into 2020, the new management team members are settling into their roles, with individual board members taking on different responsibilities. The Board of Management remains determined to build on the hard work of the previous team and to continue its work to improve the situation for homeopathic and anthroposophic medicinal products in the EU.

From left to right:
Dr Gesine Klein, David Reckeweg-Lecompte and Christiaan Mol

ECHAMP membership 2019

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



ECHAMP, the European Coalition on Homeopathic & Anthroposophic Medicinal Products, is the European association of companies that work closely together to ensure that they 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.

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