



European Coalition on
Homeopathic & Anthroposophic
Medicinal Products



An industry that continues to
serve the needs of each of its users

Annual Report 2022

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Words from the President

Millions of Europeans and healthcare professionals choose, use and recommend homeopathic and anthroposophic medicinal products.

In the aftermath of the pandemic, citizens have a renewed interest in health and well-being and are exploring health in all its forms. Those who use our medicinal products do so consciously and by choice. They tend to have higher levels of education and are eager to find partners in their healthcare practitioners – general practitioners and pharmacists – to enable them to access the best information and manage their health in a holistic way. They would like these products to be prescribed more frequently alongside conventional medicine – however, most doctors significantly underestimate the level of use of homeopathy by their patients (*see page 16*). There is a role for our industry to encourage the users of our products to inform their healthcare practitioners of their use of and preference for these products.

Today's trends in health care open up plenty of opportunities and we hope that technology, data, experience, expertise, science and common sense will come together in the right way for patients; if done well, the current review of EU pharmaceutical legislation will secure the supply chain and fulfil therapeutic needs in a way that

These therapies and their products have a clear role to play in the face of today's health challenges in the EU.

**David Reckeweg-Lecompte,
President, ECHAMP**



We have a responsibility to our users to ensure the continued supply of high quality and affordable products.

actually reaches patients. The industry now awaits the outcome of this review to be able to assess its implications for our products ([see page 5](#)). It will be essential to streamline the current rules in an efficient way so that companies have the flexibility to adapt more quickly ([see page 9](#)) and to ensure the wide availability of our products.

Like many in the pharmaceutical sector, our industry is facing the dual challenges of rising costs and disruption of the supply chain. However, with its generations of loyal users, the foundations of this industry are strong. It is rooted in the broad use and prescription of these products in all the Member States, with regulation of homeopathic medicinal products dating back to 1967 in France and 1976 in Germany, well before the introduction of the first specific EU legislation in 1992. We have a responsibility to our users to ensure the continued supply of high quality and affordable products.

European industry is the global centre of expertise for this sector and a strong local resource for the EU. It aligns itself quite naturally with current trends towards sustainable health care, a greener Europe and a One Health approach. It draws on over 200 years of experience in meeting the patient's needs, in line with the now mainstream trend towards patient-centred medicine. These therapies and their products can make an active contribution to the rapidly evolving European healthcare landscape and have a valuable role to play in the face of today's health challenges in the EU.

My colleagues on the Board and I, along with the other members of ECHAMP, look forward with confidence as we continue to play our part in the evolution of health care. We will keep on working to ensure sufficient availability of these medicines for those who use them, so that European patients can continue to access pluralism in health care and will always have the freedom to choose, use and benefit from these products.

David Reckeweg-Lecompte, President, ECHAMP



Political affairs

Accompanying the EU's journey to sustainable health

The learnings of the Covid pandemic have laid bare how fragile our health and healthcare systems can be. In today's rapidly evolving health landscape, pluralism in medicine is a key to establishing healthcare systems with fundamental long-term resilience and viability.

The highest level of public health protection can only be achieved effectively by involving patients at all levels, including in policy making.

ECHAMP believes that homeopathic and anthroposophic medicinal products can contribute to a truly holistic, patient-centred EU healthcare landscape. We encourage the Commission to adapt an inclusive attitude on the journey towards a stronger EU Health Union – one that reflects and respects the cultural diversity of the Member States and the right of each patient to have the freedom to access the health care of their choice.

Homeopathic and anthroposophic medicinal products can contribute to a truly holistic, patient-centred EU healthcare landscape.

Revision of the Pharmaceutical legislation

The ongoing revision of the pharmaceutical legislation is one of the key elements in ensuring the delivery of high quality health care and fostering innovation to meet the patient's needs.

The aims of the planned reform are to improve access to medicines and ensure a reliable supply; to encourage the development of innovative drugs; to rein in excessive costs for health systems; to minimise the environmental impact of the industry; and to streamline the regulatory process.

As we move into 2023, the pharmaceutical sector is anticipating the publication of the revised pharmaceutical legislation, to be discussed at the Council and European Parliament.

ECHAMP is monitoring developments closely. We believe that the current coherent legislative framework provides a solid base to facilitate the evolution needed in the areas targeted by the Commission. **While it is important to facilitate innovation, the best way to deliver sustainable health care to each EU citizen is to continue also to exploit the potential of existing products including homeopathic and anthroposophic medicinal products, in a regulatory framework that encompasses national competence and tradition.**

The European Parliament election in 2024 may create a hurdle for finalising the reform: EU negotiators will either have to move quickly to reach an agreement once the file is presented, or will have to wait until after the election, when a new Parliament is in place. This legislative proposal is crucial: ECHAMP recommends that the policy makers take the time to deliver the best possible future framework for the entire industry.

Digital transformation of healthcare

Telemedicine, artificial intelligence, enabled medical devices and the European Health Data Space (EHDS) are just a few concrete examples of digital transformation in health care. How we interact with health professionals, how our data are shared and the way in

which decisions are made about our treatment plans and health outcomes – these are all being completely reshaped.

The healthcare system is undergoing a seismic shift in how information is obtained and disseminated. **Patients want to be able to control and access all aspects of their health records.** In May 2022, the European Commission published a legislative proposal on the EHDS, which aims at addressing the complexity of present European rules on data sharing in the health sector and fostering digital health services across Europe.

European Commissioner for Health, Stella Kyriakides and Vice President of the European Commission, Margaritis Schinas announce the European Health Data Space



The European Health Data Space ... places the citizens at its centre empowering them with full control over their data to obtain better healthcare across the EU.

European Commissioner for Health, Stella Kyriakides

ECHAMP is following the development of the EHDS with a particular focus on the secondary use of data. This aims to provide a consistent, trustworthy and efficient process for the use of health data for research, innovation, policy making and regulatory activities. Developed standards need to allow for the specificities of each category of medicinal products, including homeopathic and anthroposophic medicinal products, so as to maximise the availability of data that can be utilised and to ensure patients have a broad choice of medicinal products. The

EHDS should enable research into Real World Data in order to be able to harness its potential.

The role of integrative medicine and health care

The trend to connect conventional and complementary medicine has continued to evolve on several levels.

European Parliament endorses the use of Integrative Medicine

ECHAMP welcomes two Resolutions from the European Parliament which recognise the benefits of integrative medicine – the [Resolution on a pharmaceutical strategy for Europe](#) (November 2021) and the [Resolution on strengthening Europe in the fight against cancer](#) (February 2022).

Manuela Ripa MEP



Integrative oncology is a therapeutic solution which aims to improve the care of cancer patients and survivors by combining conventional treatments with the best complementary therapies in coordinated and personalised treatment plans.

Manuela Ripa MEP, member of the MEP Interest Group on Integrative Medicine and Health

They highlight ‘the fact that scientifically recognised integrative medicine approved by public health authorities can bring benefits to patients in relation to the parallel effects of several diseases, such as cancer, and their treatment’, stress ‘the importance of developing a holistic, integrative and patient-centred approach’ and encourage, where appropriate, ‘the complementary use of these therapies under the supervision of healthcare professionals.’

Manuela Ripa MEP, member of the [MEP Interest Group on Integrative Medicine and Health](#), also pressed the European Commission on the topic of integrative oncology in cancer treatment with a [Parliamentary question](#).

MEP Interest Group on Integrative Medicine and Health

In June, the MEP Interest Group on Integrative Medicine and Health hosted an event at the European Parliament to discuss the [prevention and management of Covid-19 and long Covid](#). Leading experts shared their knowledge and insights on enhancing resilience as a solution for long Covid and other infectious illnesses.

Other initiatives at international level confirm this trend ([see page 17](#)). All are welcomed by ECHAMP as they endorse the fact that complementary medicines such as homeopathic and anthroposophic medicinal products have an important role to play because they aim to increase health and resilience, reduce susceptibility, and mitigate responses to infections. There is still a lot of fundamental work to be done as accessibility of these products alone will not ensure the full exploitation of their potential in the true sense of integrative healthcare.

The path to a greener Europe

The European Green Deal, approved in 2020, is a set of policy initiatives to transform the EU into a modern, resource-efficient and competitive economy, ensuring no net emissions of greenhouse gases by 2050, that economic growth is decoupled from resource use and that no person or place is left behind.

ECHAMP encourages the Commission to acknowledge the commitment and ongoing efforts of the pharmaceutical sector in further reducing the environmental risk of medicinal products.

As part of this, the revision of the Directive on urban waste water treatment contributes to the Zero Pollution Action Plan. The current Directive dates from 1991 and the need to address the removal of micro-pollutants is without doubt a necessity. Our sector believes firmly that our health depends on our environment and that an unhealthy environment has direct and costly consequences for our health. Nevertheless, it seems that the Commission's proposal, which specifically targets the pharmaceutical industry in the revision of the Directive with the proposal to have it finance water treatment upgrades, is not only disproportionate but will be detrimental to patient access to medicines. ECHAMP encourages the Commission to acknowledge the commitment and ongoing efforts of the pharmaceutical sector in further reducing the environmental risk of medicinal products.



Regulatory affairs

ECHAMP follows regulatory developments carefully, reacting to new or amended provisions that will affect the availability of homeopathic and anthroposophic medicinal products. We aim to ensure that the relevant specificities of our products are highlighted so that they can be taken into consideration.

Towards flexible and efficient approaches

ECHAMP aims to ensure that the relevant specificities of our products are highlighted so that they can be taken into consideration.

In its Pharmaceutical strategy for Europe, the European Commission indicated the need for simplification and streamlining of procedures in areas such as the management of variations and the assessment of quality files. ECHAMP welcomes the upcoming review of EU rules on changes to marketing authorisations which will address the current rules on procedures for post-authorisation changes to a marketing authorisation for medicines for human use (variations), with the goal of making the lifecycle management of medicines more efficient.

ECHAMP will support this initiative, with the aim of reducing the regulatory burden for our sector.

Licensed homeopathic and anthroposophic medicinal products meet the highest standards for quality and safety and are produced according to Good Manufacturing Practice.

The industry for homeopathic and anthroposophic medicinal products is characterised by unique levels of variety and complexity. Prescribers generally need a broad choice of distinct source materials (up to 3,000) for the comprehensive practice of



these therapies and some larger manufacturers source as many as 2,000 starting materials, from over 100 different suppliers. These important facts are communicated by ECHAMP whenever it comes to any new requirements which could have a negative effect on the availability of raw materials.

The industry needs the current rules to be more streamlined for these products to allow the companies the flexibility to adapt more quickly. There are options that meet the quality requirements while at the same time minimise redundant information. In this way, the associated workload for both competent authority and pharmaceutical company can be reduced without impairing data transparency or the quality and safety of the medicinal product.

A balanced approach is necessary to reduce the regulatory burden. We will participate in the consultation to ensure the complexity of our sector is taking into proper consideration.

A balanced approach is necessary to reduce the regulatory burden.

Homeopathic Medicinal Products Working Group

Meetings between industry and the Homeopathic Medicinal Products Working Group (HMPWG) help foster a shared understanding of the daily practice of the manufacturing of homeopathic and anthroposophic medicinal products. Since its previous industry dialogue in 2018, ECHAMP continues its close collaboration with other industry associations and hopes to engage in fruitful dialogue with medicinal agency representatives in the near future.

Guidance documents for Quality

In April 2022, ECHAMP responded to two consultations from HMPWG on guidance documents for Quality.

The first one (new Question 9) relates to Good Manufacturing Practice (GMP) provisions. ECHAMP believes the provisions should respect the importance of very small entities as sources for raw materials and the limited availability of atypical materials for these medicinal products.

Question 13 addresses the question of stability. ECHAMP believes (see also above) that measures could and should be taken to reduce the regulatory burden for the companies. The manufacturer already has responsibility to comply with GMP and it is therefore not necessary for all the details also to be required in the application dossier. We also ask the authorities to accept approaches that are already implemented in other EU countries.

We will continue to submit comments and share our expertise with HMPWG as needed.

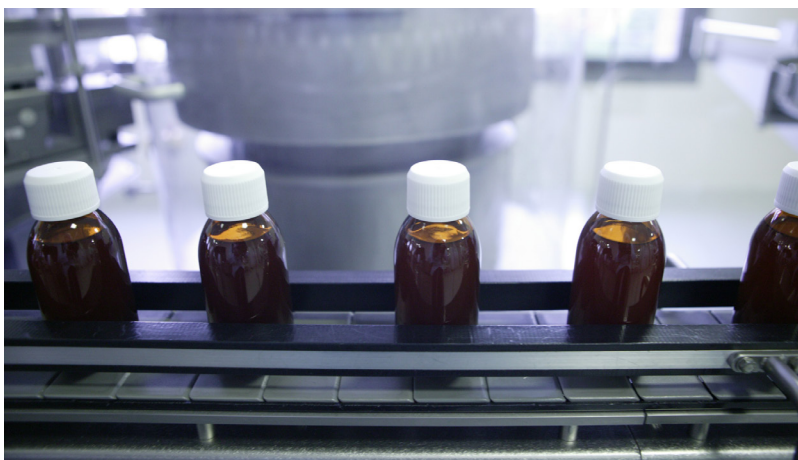
EMA's master data for identifying a medicinal product

ECHAMP continues its work with the European Medicines Agency (EMA) task force on substance, product, organisation and referential master data for the identification of a medicinal product (IDMP/SPOR).

The focus of the EMA working groups, which are now working in an agile manner, is on the Product Management Service (PMS) and the Substance Management Service (SMS). In particular, work is underway on the use of PMS data in the Digital Application Dataset Integration/Product Lifecycle Management Portal (DADI/PLM) system. In this field, ECHAMP is contributing expertise for homeopathic and herbal products and supports the development of usage standards for these products.

ECHAMP also participates in the sub-working group for the SMS and the linked EU – Substance Reference System (SRS) for homeopathic and herbal substances, in cooperation with EMA and the German and Dutch medicines agencies (BfArM and CBG). In this group, a guide for the standards required for these specific substances was worked out and presented to the HMPWG.

Prescribers generally need a broad choice of distinct source materials (up to 3,000) for the comprehensive practice of these therapies.



Anthroposophic medicinal products: A literature review for scientific and regulatory assessment

A new study presents a comprehensive review of scientific information on anthroposophic medicinal products, with the aim of providing sufficient information on these products for the scientific community and the regulatory authorities. It confirms ECHAMP's goal to improve the pharmaceutical framework for these products in the EU.

Anthroposophic medicinal products form a distinct group of medicinal products. Some overlap with herbal and homeopathic medicinal products regarding ingredients and manufacturing procedures, while others are manufactured using specialist procedures. These specific features mean that their scientific and regulatory assessment can be challenging.

The study concludes that anthroposophic medicinal products are part of the integrative whole medical system of anthroposophic medicine. They are manufactured according to GMP and national pharmaceutical regulations and have an excellent safety status; the available evidence suggests clinical benefits. The current pharmaceutical framework for anthroposophic medicinal products in the EU and most European countries does not address the special properties of these products.

India: New Drugs, Medical Devices and Cosmetics Bill

The Indian Ministry of Health and Family Welfare (MOHFW) is revising the Drugs, Medical Devices and Cosmetics Bill with a view to develop a more contemporary legislation.



Complementary medicine has always been an integral cornerstone in India's health system, with its long-standing pluralistic approach to healthcare, and the revision presents a unique opportunity for India to facilitate innovation for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) medicines and to engage in the global development of this sector.

However, there is a risk that the draft Bill may inadvertently discriminate against homeopathic products, firstly, through possible restrictions of manufacturing techniques to those of the Indian Homeopathic Pharmacopoeia (HPI) and secondly through highly increased registration and import fees. This could mean that products manufactured in accordance with other homeopathic pharmacopoeias, some of which have been on the Indian market for decades, may no longer be available for the Indian population. Continued recognition of currently recognised homeopathic pharmacopoeias is essential to preserve the existing market and ensure the availability of those products.

ECHAMP has written to the Ministry to ask it to take into consideration the concerns of its Members.

European Pharmacopoeia: Setting standards

The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe continues its essential work on the standards for homeopathic medicinal products through the work of the European Pharmacopoeia (Ph. Eur.).

Quality standards give a solid basis on which to enter the market either through submitting dossiers for a marketing authorisation or registration or in order to manufacture magistral preparations. They provide the authorities with a legal instrument by which to review the quality. This helps in turn to reinforce the sound legal framework for these medicinal products.

The commitment to the continuous evolution of quality standards for homeopathic manufacturing methods and preparations and to harmonisation are essential to the future of our industry, enabling us to deliver medicinal products of the highest quality throughout Europe and the rest of the world and therefore making a valuable contribution to the growing field of integrative medicine.

The European Pharmacopoeia and its Working Parties

ECHAMP continues to appreciate and support the considerable efforts of the European Pharmacopoeia (Ph. Eur.) and its Working Parties, following this work with careful attention, sending expert comments to EDQM drafts, attending relevant events and offering input to the further development of the European Pharmacopoeia monographs.

2022 saw a number of concrete steps towards this goal of harmonisation:



ABOVE **Hyoscyamus**
BELOW **Stramonium**



Guide for the elaboration of monographs

BELOW Bryonia, Mandragora

EDQM approved the first update of the Guide for the elaboration of monographs on homeopathic preparations. This guide lays the basis for all monographs, defining the preparation and allowing for the proper identification of homeopathic preparations. It now includes examples drawn from the latest new monographs and has been updated in line with the new Ph. Eur. policy on assays. An assay continues to be required for toxic stable components but a limit test can be used instead of an assay for unstable toxic components.

In the future, for non-toxic components, the assay could be replaced by a semi-quantitative fingerprint determination of at least two appropriate markers.

One such approach might be the use of high-performance thin-layer chromatography. A pilot phase on this technique is still ongoing, with three substances defined: Calendula, Herba; Chamomilla, Herba; and Arnica, Planta tota. There is good progress in the work with Calendula at an advanced stage. For now, this specific possibility has not yet been included in the updated guide; however we are optimistic it will lead to a robust identity and quality test.

Six new monographs

After several years of intense work towards European harmonisation, six new or updated monographs have now been adopted and will be implemented from January 2023. They include Hyoscyamus, Mandragora, Bryonia, Ephedra, Stramonium and Ferrum metallicum.

ECHAMP applauds the fact that both the French and the German homeopathic traditions are now well reflected in these monographs.

Manufacturing methods

2022 also saw the introduction of tinctures manufactured by fermentation (the Rh-manufacturing process) into the Ph. Eur. under the monograph: Methods of preparations of homeopathic stocks and potentization (2371) method 1.5.1 and 1.5.2.



International collaboration

Harmonisation and legal recognition are shared goals between the world's pharmacopoeias and EDQM plays a central role in continuing to set high quality standards for all medicinal products in the changing global context.

ECHAMP recognises the increasing importance of this cooperation. In many parts of the world, such as Central and South America (e.g. Mexico and Brazil) and India, herbal medicines and homeopathic medicinal products play an important role in their medical tradition and this is reflected in their pharmacopoeial standards.

ECHAMP welcomes the increasing involvement of the Indian Pharmacopoeia Commission in the work of EDQM and its inclusion as a participant in the Pharmacopoeial Discussion Group (PDG) pilot for global expansion. We anticipate this will have a positive impact on the further recognition of the European Pharmacopoeia outside the EU.

Anthroposophic Pharmaceutical Codex

The International Association of Anthroposophic Pharmacists (IAAP) has published the fifth edition of the Anthroposophic Pharmaceutical Codex (APC), documenting and confirming the quality standards for the manufacture of anthroposophic medicinal products. It provides an overview of the pharmaceutical processes and substances used in the manufacture of anthroposophic medicinal products and the related quality parameters, describing the main anthroposophic manufacturing methods and the substances used in anthroposophic medicine, referencing other Pharmacopoeia where possible.

14 new substances have been added to the appendices.

Tinctures manufactured by fermentation

SOURCE: WELEDA



Users of homeopathy

Use of and trust in homeopathic medicinal products remains high

The most recent market studies confirm that millions of European citizens choose to use these products and therapies for their health care. In countries where awareness is high, use of and trust in the products is also high.



- Seven out of ten are very or somewhat convinced of the benefits of homeopathy
- Four out of five have taken homeopathy at some point in their life and two out of five have been using homeopathy for more than 10 years
- Over half say they use homeopathy compared to only one third who use other forms of complementary medicine



- 70% of people have an open attitude towards homeopathy – over half have tried homeopathy and an additional 16% are open to trying it



- 71% of respondents of Campania in South-West Italy had heard about homeopathy
- One in five used it at least once a year, and on average had been using it for more than five years



- Over 60% have used complementary medicine, with homeopathy the most popular treatment – four in ten people have used it

- Patients report a high level of satisfaction with homeopathic and anthroposophic medicine treatment. They choose these products for their effectiveness and high safety profile and to avoid the adverse side effects of chemical products.
- Users tend to be female with higher levels of education.
- Word-of-mouth recommendation from friends and family is still the main reason people try homeopathy, although recommendations from doctors and pharmacists are also important.
- Patients want their general practitioners and pharmacists to be able to provide information on homeopathy and would like doctors to prescribe homeopathic medicines more frequently, alongside conventional medicine.
- Health professionals and doctors significantly underestimate the level of use of homeopathy by their patients.

For references [visit the ECHAMP website](#)

Around the world



The Austrian government's national Action Plan on Anti-microbial Resistance confirms the potential of homeopathy, other complementary medicines and integrative medicine in tackling antimicrobial resistance.

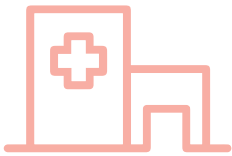


Homeopathy Research Institute hosted an international online event, Key collaborations in homeopathy research for 450 experts from 35 countries. The 75th World Congress of Homeopathy was held in Istanbul, organised by the International Homeopathic Medical League (LMIH).



Some vocal attacks in the media from critics of homeopathy in 2022 demonstrate a prevailing bias against homeopathy by some press and research institutions; this is denying patients and society objective facts and reporting.

ECHAMP was pleased that a public debate on reimbursement in Germany in 2022 resulted in the decision that the current law will stand.



The anthroposophic community hospital, Havelhöhe, has topped a list of Berlin hospitals and is among the top five hospitals in Germany.



A worldwide community of users and practitioners of traditional, complementary and integrative healthcare (TCIH) have come together to publish a common declaration, calling for a person-centred and holistic approach to healthcare.

In Norway, critics are taking advantage of a review of legislation governing pharmacies to lobby for a review of the current arrangements for homeopathic medicinal products which may have an impact on the sale of these products. However, pharmacists will not be prohibited from selling them.



The World Health Organization announced the establishment of a new Global Centre for Traditional Medicine in collaboration with the Government of India.

Inside ECHAMP



ECHAMP has 35 Full Members from 14 EU Member States plus Norway and four Extraordinary Partners from Switzerland and UK, all company members active in the production and distribution of homeopathic and anthroposophic medicinal products (*see map of Members on page 20*); there are 11 Associated Partners (national manufacturers' associations) from eight EU Member States, UK and Switzerland and 10 Corresponding Partners (practitioners' and patients' organisations).

ECHAMP's members meet in working groups to develop policy positions on important issues, drawing on their competence and daily experience to publish responses and position papers, develop initiatives, propose and organise events and negotiate with decision makers and other stakeholders. ECHAMP's main fields of activity are Political Affairs, Regulatory Environment, Pharmacopoeia and Public Relations & Communication.



In 2022, David Reckeweg-Lecompte was re-elected ECHAMP's President for a second three-year term. Board member of ECHAMP since 2016, David has been Managing Director of Dr Reckeweg, Germany since 2013. After no in-person meetings for over two years because of the pandemic, the Board of Management was finally able to meet in person and looks forward to more such meetings, including the annual Membership Assembly, in 2023.



ECHAMP's 22nd annual Membership Assembly in April brought together online Members from 14 countries across Europe. Members were updated on the EU Pharmaceutical Strategy and the revision of the Pharmaceutical Legislation, the Green Deal and sustainable corporate governance and given an overview on the latest developments in research and science in both homeopathy and anthroposophic medicine.



In October, ECHAMP organised a webinar for the regulatory experts of our Members on the registration or authorisation of notified homeopathic medicinal products in Spain, comparing the experience to that of Italy.



ECHAMP issues ad hoc updates on news and events in the world of homeopathic and anthroposophic medicinal products and a monthly update for Members on our activities, with internal alerts on sector issues that need special attention.



ECHAMP hosts active pages on both [Twitter](#) (@ECHAMPeu) and [LinkedIn](#), monitoring and promoting events and developments of relevance to the industry and the sector.

About ECHAMP

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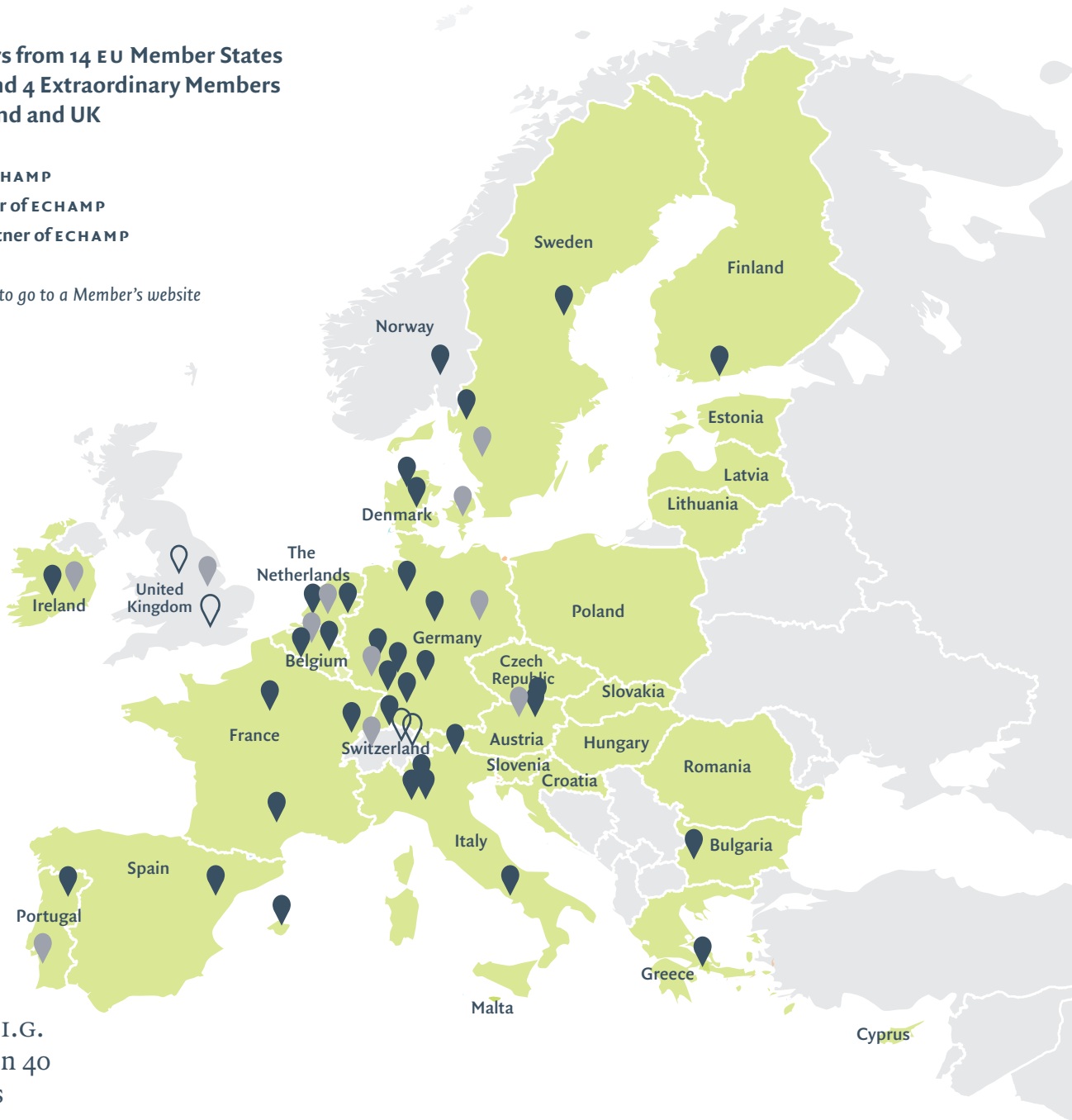
ECHAMP members

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.

35 Full Members from 14 EU Member States plus Norway and 4 Extraordinary Members from Switzerland and UK

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

Click on each flag to go to a Member's website



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