ECHAMP

European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

Serving users and prescribers

ANNUAL REPORT 2023

ECHAMP – an expert industry association

In 2023, the sector for homeopathic and anthroposophic medicinal products was able to benefit, once again, from the extensive expertise and experience of ECHAMP and its members, built up over many years of close collaboration.

This annual report provides an overview of another busy year for our industry, as we are following the draft legislative texts revising the pharmaceutical legislation and the amendments of the European Parliament, submitting our comments to both European institutions (*see page 3*). We have continued to give input and support to those working to uphold an appropriate regulatory environment (*see page 5*) and to define and implement homeopathic pharmaceutical standards (*see page 6*), so as to ensure the quality and safety of our products.

We call on MEPs for their support in protecting access to these medicines

David Reckeweg-Lecompte, President, ECHAMP

Our goal is to ensure that our member companies can meet the demand from users and prescribers across the EU for homeopathic and anthroposophic products. In this, we collaborate closely with other industry and stakeholder associations, as part of a strong alliance of those with an interest in developing this sector.

2023 was an important milestone on the international stage, as both the World Health Organization and the G20 leaders gave formal recognition to the potential of traditional, complementary and integrative medicine to contribute to broader healthcare goals; we applaud these initiatives, which set a positive global context for our medicinal products. The latest studies confirm that millions of European citizens choose and have confidence in the use of these products as part of their health care. These are strong messages for politicians and policy makers, and as we look forward to the European elections in 2024, we call on MEPs for their support in protecting access to these medicines.

The strength of our sector comes from the dedication and efforts of all those within it – industry, patient, prescriber and scientific associations – and from committed politicians and policy makers, working at national, European and international level. We work together to strengthen and develop the industry and to secure its future, so as to ensure the continued supply of high quality and affordable homeopathic and anthroposophic products for the European citizens who choose to use them.

David Reckeweg-Lecompte,
President, ECHAMP

Revision of the EU Pharmaceutical Legislation

On **26 April**, the European Commission published for public consultation the draft legislative texts for the ***revision of the pharmaceutical legislation***.

In ECHAMP's ***response***, we:

- welcome the Commission's initiative to maintain the dual format of regulation and directive. This will continue to facilitate the needs of patients who use homeopathic medicinal products, balancing the quality and safety of these products with European citizens' access to the medicines they require;
- welcome the proposal in the **draft directive** to preserve the existing provisions for homeopathic medicinal products without changing their substance (*preamble 4*), in line with previous efforts on harmonisation in Directive 2001/83/EC and applicable standards as set down in the European and national pharmacopoeias;
- ask the Commission to confirm that anthroposophic medicinal products described in an official pharmacopeia and prepared by a homeopathic method, referred to in preamble 22 of Directive 2001/83/EC, are also covered by preamble 4, so that the intent of these provisions is unambiguously carried forward, acknowledging the long-standing European tradition of these medicinal products;
- recommend the use of broad definitions of data sources concerning real world data and real world evidence so as to ensure maximum inclusion of patient experience in all related decisions;
- highly recommend close collaboration with industry as regards environmental risk assessment and mitigation associated with pharmaceuticals, in order to leverage all available data to assist with prioritisation and avoid duplication of work;
- recommend that the provisions in the **draft regulation** for the monitoring and management of shortages and critical shortages be aimed at medicinal products on the lists of critical medicines, so as to avoid generating an unintended and purposeless administrative burden either for marketing authorisation holders or for competent authorities.

September marked the start of the deep dive into the proposals by the Members of the European Parliament and the EU Member States. ECHAMP is actively advocating on the amendments which impact the status of homeopathic medicinal products endangering the future of our industry.

Variations consultation and ECHAMP response

In **August**, the European Commission published a ***Call for Evidence***, the aim of which is to gather insight from all impacted stakeholders so as to underpin the Commission's revision of the changes to marketing authorisations (***Variation Regulation (EC) 1234/2008*** – the variation framework for medicines). This was first announced by the Commission in October 2022 as part of their ***Work Programme 2023***.

In our ***response***, we welcomed this Commission initiative to revise the variation framework for medicinal products. It acknowledges the request from industry and the regulatory authorities for improvements to be made to the current framework in terms of efficiency and flexibility. Today a disproportionate amount of resources is required to maintain marketing authorisations. We therefore appreciate that the Commission sees the need for a short-term solution under the existing legislation.

We took the opportunity to bring to the Commission's attention a number of sector specific challenges, bringing some proposals for amendments, fully understanding the need to maintain data transparency and current quality and safety standards.

For reasons of proportionality, homeopathic medicinal products subject to a simplified registration procedure are excluded from the scope of the Regulation. However, the variations regulation continues to be referenced by many Member States for simplified registrations as well those with a marketing authorisation. This revision is therefore of high interest to our industry, not only for those products in the marketing authorisation category but also for those in the simplified registration category. We hope it will deliver significant benefit to our industry.

Copies of ECHAMP responses to Commission consultations are available on the ***ECHAMP website***.

HMPWG: a meeting with industry and a new report

On **29 March**, a joint virtual meeting took place between the Homeopathic Medicinal Products Working Group of the Heads of Medicines Agencies (**HMPWG**) and industry, represented by ECHAMP, AESGP and EUCOPE. It was hosted and chaired by the Swedish medical products agency. We all appreciated greatly the professional approach and the open, transparent and cordial atmosphere.

Industry gave two presentations, one on the need for **lean application** (that is a streamlined application that avoids duplication of information) and one on the specific challenges of the current **variations regulation** (*see page 4*). Both are subjects of high interest to our sector. The presentations were followed by a question and answer session which gave us the opportunity to share concrete examples on both topics.

The HMPWG Chair welcomed the industry perspective and the 'reality check' on what all agreed were difficult points. It was clear that due to the national implementation of the relevant legislation, some Member States continue to require more details than others.

At ECHAMP, we continue to support the work of HMPWG, and acknowledge their resource constraints. We were pleased to have the opportunity to reconnect with the HMPWG experts, and to share our experience of the practical impact of specific issues by using concrete examples.

In **October**, by way of follow up, ECHAMP informed HMPWG that our response to the European Commission's consultation on the revision of the variation framework (*see page 4*) for medicines is based on the information shared with them in the March meeting.

Update report on regulatory status

In **April**, we were happy to receive an updated *report from HMPWG* on the regulatory status of homeopathic medicinal products for human use. It includes answers from the national competent authorities to specific questions on homeopathic and anthroposophic medicinal products in the EU and EFTA markets. The report provides an invaluable, comprehensive and reliable summary of the regulatory situation for these products.

EDQM and the European Pharmacopoeia

ECHAMP Members follow closely the important and ongoing work on the implementation of homeopathic pharmaceutical standards in the European Pharmacopoeia Monographs.

Meeting with EDQM

On 4 December, ECHAMP met with the management of the European Directorate for the Quality of Medicine and Healthcare (EDQM). Such bilateral meetings offer an essential opportunity to exchange and learn from each other.

We discussed the EDQM work on the pilot on semi-quantitative high-performance thin-layer chromatography (HPTLC) for non-toxic substances, which focuses on three substances: Calendula, Herba; Chamomilla, Herba; and Arnica, Planta tota. ECHAMP strongly recommended that sufficient attention is given to the robustness of the practical implementation of the method before finalisation.

The work on the substance monographs is positive and important. At the same time we are advocating for an update of the list of substances, so as to prioritise those which would be most beneficial for industry and the regulators. The list could reflect the current market relevance and ensure the best use of resources.

The work on the draft monograph Phosphorus is also extremely important for our industry. Now that the equivalence of the two proposed analytical methods has been successfully demonstrated, we hope that the monograph publication will be released soon.

The manufacturing methods working group has completed the work set out and is at the moment dormant. However, our industry is looking to the future and is ready to innovate. We will request the reactivation of the working group, should there be a need to address new data.

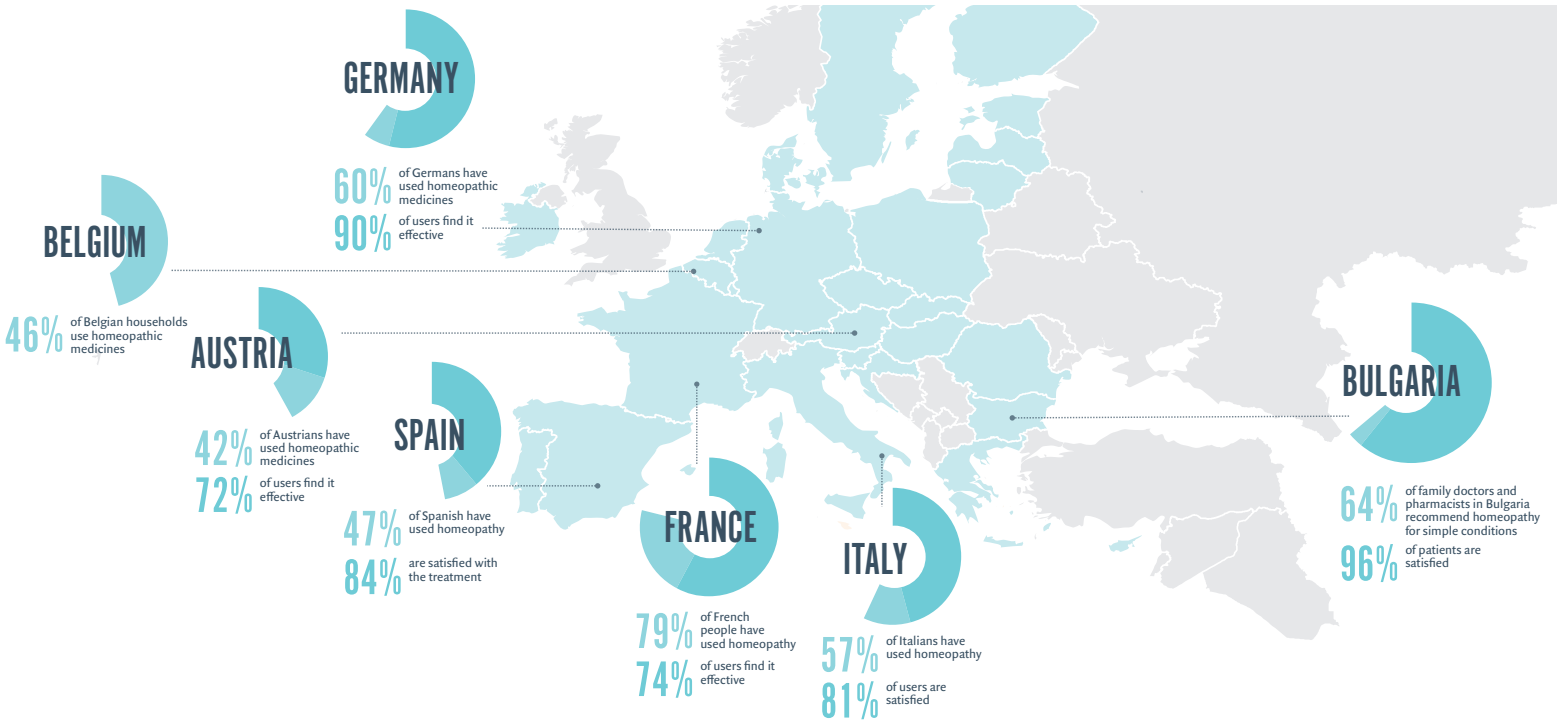
Consultations

The valuable work to integrate homoeopathic pharmaceutical standards in the European Pharmacopoeia Monographs continues, with the welcome publication of the draft monographs: 'Crocus for Homoeopathic Preparations' published in *Pharmeuropa* 35.2; 'Cuprum aceticum for homoeopathic preparations'; and 'Iberis amara for homoeopathic preparations' published in *Pharmeuropa* 35.4.

ECHAMP publications

In 2023, some new publications from ECHAMP provided valuable information for the sector for homeopathic and anthroposophic medicinal products. These are all available on our ***website***.

- *Homeopathic and Anthroposophic Medicinal Products in the EU – Who uses them and why* provides a unique European profile of the users of homeopathic and anthroposophic medicinal products, their choices and their needs. It confirms that millions of European citizens choose and have confidence in the use of these products for their health care.
- An infographic map draws on the latest market data to demonstrate the widespread use of and satisfaction with homeopathy in the EU.
- *Homeopathic and Anthroposophic Medicinal Products in the EU – The added value of the sector* provides a comprehensive summary of the current evidence base for these therapeutic systems and their related products and outlines the role that they can play in the face of today's health challenges in the EU. It demonstrates the significant added value to society of homeopathy and anthroposophic medicine.
- A one-page summary, *Support the People's Choice*, outlines ECHAMP's key messages on the value and importance of our industry for politicians and policy makers, in preparation for the European Parliament elections.



ECHAMP: support for our members

ECHAMP supports the business of our members by ensuring a stronger voice for the common interests of the sector at European level, giving them access to a wealth of expertise and resources, and helping them stay up to date with the latest developments affecting the sector. In 2023, support for our members included:

Information for our members and other sector stakeholders

- **ECHAMP News**: adhoc news items on developments concerning homeopathic and anthroposophic medicinal products in the EU
- **Social Media**: information on our activities and campaigns and those of our allies via LinkedIn and X
- **Member Alert**: urgent news or updates for ECHAMP Full Members and Extraordinary Partners
- **Members' Update**: monthly internal news on the association's activities.

Three internal webinars for the regulatory experts of our members

- **January**: Lifecycle management and our sector: the theory and practice, in view of the upcoming review of EU rules on variations (*see page 4*);
- **June**: the assessment of the draft texts for the General Pharmaceutical Legislation (*see page 3*); and the legislative process and the impact of the upcoming European election (June 2024)
- **October**: an update on the IDMP/SPOR Data Management Service.

Membership Assembly

In **April**, in Sofia, Bulgaria: our first in-person meeting in four years, for ECHAMP members and local stakeholders – networking, discussion and social activities:

- **'Homeopathy in Bulgaria**: Experience and best practice,' chaired by Nonna Petrova of Alpen Pharma with Ass. Prof. Vladimirova, National Centre for Public Health and Analysis, and Dr Dora Pochova, Chair of the Association of Homeopathic Physicians.
- **'Trends in Healthcare**: The rising of the integrative agenda', with Prof. Dr Eran Ben-Ayre, Co-founder and Director, Unit of Complementary and Traditional Medicine, Department of Family Medicine, Haifa, Israel; followed by a lively discussion on the opportunities and challenges the rapidly evolving healthcare landscape presents for the industry with Dr Ton Nicolai, Honorary Secretary-General of EUROCAM, Dr Dora Pachova, Dr Monica Mennet von Eiff, member of the Board of Management of ECHAMP, and Ian Wilders, Director of ExNarrative.
- **The annual Membership Assembly**, chaired by Dr Nonna Petrova.

Around the world

Manuela Ripa MEP

Sirpa Pietikäinen MEP

WHO and the G20 leaders recognise the potential of traditional and complementary medicine

In 2023, the World Health Organization (WHO) and the G20 leaders gave recognition to the potential of traditional, complementary and integrative medicine (TCIM) to contribute to broader healthcare goals. We support WHO's commitment to apply rigorous scientific methods to ensure effectiveness and safety in the use of these systems, and believe there is a real need to invest in better understanding of these medical systems.

- **August**: the first WHO Traditional Medicine Global Summit, 'Towards health and well-being for all', in Gujarat, India, reaffirmed previous global commitments related to TCIM, and set forth ambitious goals for harnessing the contributions of TCIM for health and well-being, including the application of science, technology, innovation and knowledge exchange.
- **September**: in New Delhi, the G20 leaders recognised the potential role of evidence-based TCM, taking note of international efforts in this direction.

The People's Declaration for Traditional, Complementary and Integrative Healthcare (TCIH) continue their persistent and valuable work behind the scenes which helped to bring these issues to the top of the agenda.

MEP Interest Group on Integrative Medicine & Health

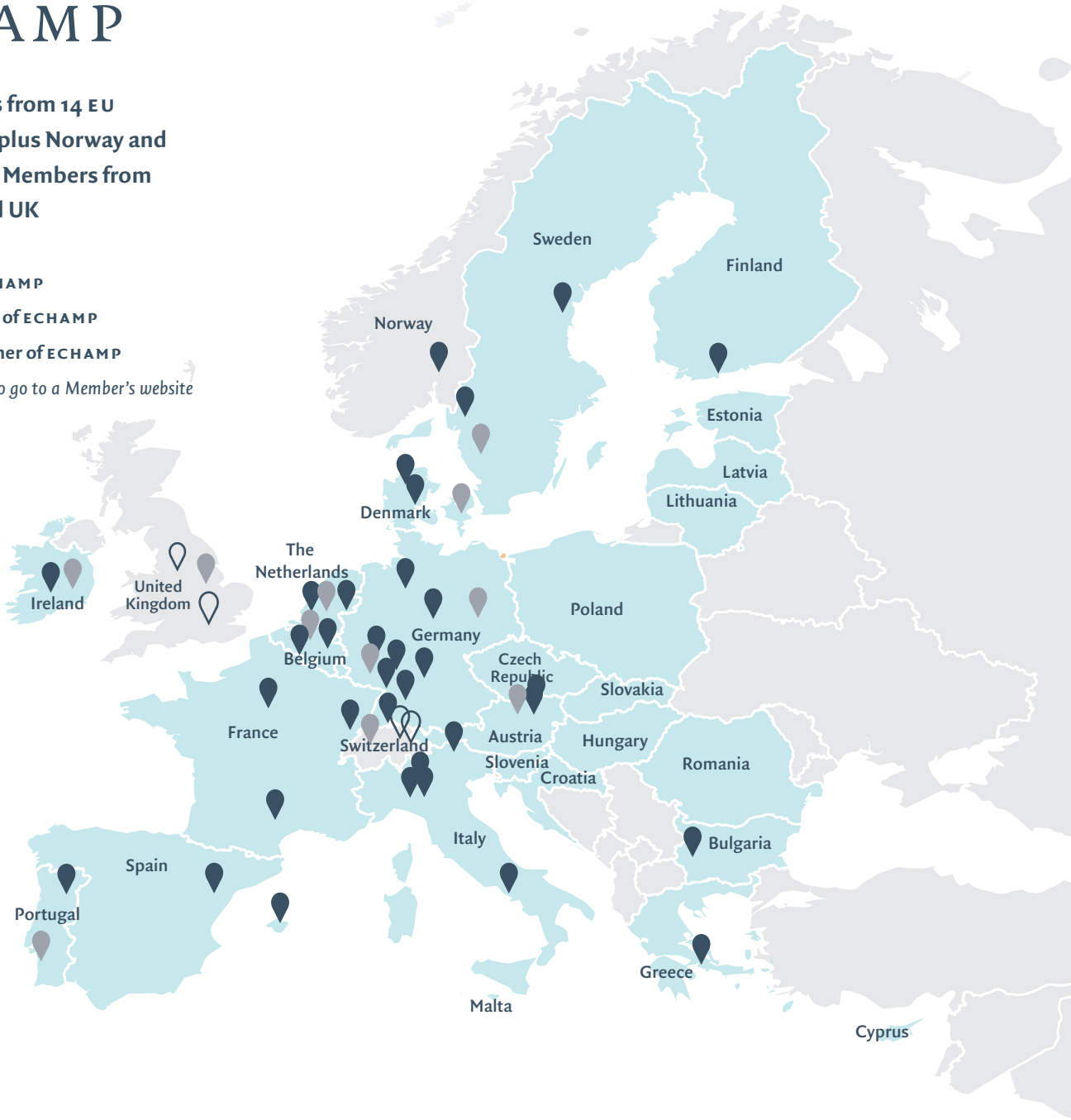
A group of Members of the European Parliament, active in the field of integrative medicine, hosted two important meetings in the European Parliament in 2023. These confirm the relevance and importance of this sector and its potential to contribute to EU health priorities:

- **March**: *Integrative Mental Health – the way forward*: experts working at the intersection of mental health and TCIM shared evidence-based solutions and explained the practical benefits of applying TCIM in this important area. The event was opened by MEP Interest Group Co-chair ***Sirpa Pietikäinen***, and closed by MEP ***Maria Walsh***, Co-chair of the MEP Alliance for Mental Health.
- **June**: 'The role of Integrative Oncology in improving cancer treatment outcomes for patients': hosted by MEP Interest Group Co-chair ***Manuela Ripa***, the meeting provided a forum for leading experts to share their knowledge and experiences on best practices for integrating different medical traditions into mainstream cancer care.

About ECHAMP

31 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 to go to a Member's website



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ECHAMP members

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