Celebrating 25 years and embracing the future

ECHAMP

European Coalition on Homeopathic & Anthroposophic Medicinal Products

ANNUAL REPORT 2024

President's statement

In 2024, ECHAMP, the European association dedicated solely to homeopathic and anthroposophic medicinal products, proudly marked its 25th anniversary. This milestone celebrates a quarter-century of fruitful collaboration amongst its members, the manufacturers and distributors of homeopathic and anthroposophic medicinal products. This strong foundation sets the stage for the next chapter.

This year 2024 was also marked by the focus on the extremely important revision of the pharmaceutical legislation (*see page 5*). ECHAMP remains a strong advocate for maintaining the legislative framework and its related obligations which safeguard the safety of the European patient. A change of the current legislative provisions for our products could potentially lead to a resurgence of challenges for the medicines agencies and the industry which were previously resolved by Directive 92/73/EEC and 2001/83/EC.

Throughout the year, ECHAMP actively participated in consultations on relevant technical, regulatory and pharmacopoeial documents (*see page 7*) and also submitted comments to the World Health Organisation on its draft traditional medicines' strategy 2025-2034 (*see page 8*).

As ECHAMP continues its advocacy activities, the team engaged in strategic discussions with the ECHAMP Board of Management and the Members on shaping the future of the association. Moving forward, ECHAMP will focus on political and regulatory matters specifically relevant to homeopathic and anthroposophic medicinal products to continue being a reliable partner for the European Legislator. Monitoring legislative changes, such as the ongoing review of the Directive 2001/83/EC, remain the priority.

Reflecting on its proud history, ECHAMP eagerly anticipates a new and exciting chapter, with continued dedication to serving its members and paving the way for a brighter future for the sector.

David Reckeweg-Lecompte, President

25 years of ECHAMP, reflecting on the past with pride and looking forward to the future with confidence.

David Reckeweg-Lecompte, President, ECHAMP

European political landscape

The European elections were held in the European Union (EU) in June 2024. A total of 720 Members of the European Parliament (MEPs) were elected to represent more than 450 million people from 27 Member States.

While the general perception on the ground in Brussels is that health has been downgraded in the list of Union priorities, Members of the European Parliament and its committee (SANT) focusing solely on Public Health are taking note of the importance of health to the European Citizens. ECHAMP very much hopes that they will also listen to the wish of patients to have a health system which encompasses integrative medicine and care.

The European Commission appointed Mr Olivér Várhelyi as Commissioner for Health and Animal Welfare. He is in charge of bringing the revision of the Pharmaceutical Legislation to a conclusion and mediating the position of the European Parliament and Council. ECHAMP will monitor his approach closely.

Revision of the Pharmaceutical Legislation

On 10th April, the Members of the European Parliament (MEPs) adopted their position on the proposed revision of the Pharmaceutical Legislation. It includes a proposal for a modification of the reference 'homeopathic medicinal products' to 'homeopathic products' in all relevant articles and the introduction of a review clause regarding the provisions relating to homeopathic medicinal products.

The implementation of this proposal would directly impact on the packaging and labelling of approximately 20,000 products currently licensed. A resource and financial burden for this industry sector which would be clearly disproportionate even without estimating the

ECHAMP Members believe that the current legislative framework and its related obligations provides the European patient with access to high quality safe products of their choice.

← Dolors Montserrat, rapporteur for the pharmaceuticals directive
↑ Olivér Várhelyi, New Commissioner for Health and Animal Welfare

capacity needed on the side of the national medicines agencies, not to mention the negative sustainability effect. This at a time when resources are already stretched and a call for a review has also been tabled by MEPs.

This kind of disproportionate effort for both industry and competent authorities should be avoided, in line with the regulators 'evaluate first' principle.

It is now the turn of the Council to formulate its position on the Commission's proposal before the start of the negotiations between the three Institutions can commence. In these discussions, ECHAMP hopes that the Member States choose to preserve the current effective legislation framework and follow the EU Commission proposal to leave the provisions for homeopathic medicinal products out of the scope of this revision. The current comprehensive legislative framework for the homeopathic medicinal products industry has made the EU the global centre of expertise in manufacturing and quality standards, with a proven track record on patient safety.

A change of the current provisions could potentially lead to a resurgence of challenges previously resolved by Directive 92/73/EEC and 2001/83/EC. This would be a legislative step back and specific challenges that have already been resolved through coherent legislation would be back on the table.

The European legal and regulatory medicinal products framework guarantees for homeopathic medicinal products, as for all medicinal products, through several mutually reinforcing activities, the quality and safety of these products, and therefore patient safety. It encompasses licensing obligations for manufacture, import, export and distribution, with inspection and surveillance, licensing obligations for market access, post-marketing control measures, including pharmacovigilance, and requirements for the provision of independent information.

ECHAMP Members believe that the current legislative framework and its related obligations provides the European patient with access to high quality safe products of their choice.

EU Pharmaceutical landscape

This year again, ECHAMP answered public consultations on technical and regulatory issues.

The Homeopathic Medicinal Products Working Group

The Homeopathic Medicinal Products Working Group (HMPWG) of the Heads of Medicines Agencies (HMA) released two documents for public consultation.

The first document is the revision of the 'guidance on module 3 of the homeopathic medicinal products dossier'. The module 3 of the Common Technical Document (CTD) focuses on the quality of the medicinal product. The aim of this document submitted for public consultation is to provide guidance on compiling information for an application dossier for homeopathic medicinal products (HMPs) and to try to harmonise the dossier template requirements for HMPs to facilitate the mutual recognition procedure amongst the EU Member States. This revision consolidates in one document the existing requirements throughout the EU and introduces a number of new ones. While the proposal is very detailed, it lacks precise definitions of terms: ECHAMP feels that more consideration should be taken of the Heads of Medicines Agencies List of terms used in homeopathy to avoid misinterpretation by Competent Authorities. ECHAMP is also concerned about the lack of distinction between GMP (Good Manufacturing Practice) requirements and the registration dossier requirements, which could lead to an unnecessary increase of administrative burden. ECHAMP submitted detailed comments on this proposal.

The second document is the revision of the 'Questions and answers document on the quality of homeopathic medicinal products with the addition of Q 14-15 on the investigation and risk assessment requirements in the case nitrosamine contamination' suspected by the Marketing Authorisation and/or Registration holders. ECHAMP was satisfied with the proposal.

European Medicines Agency

The European Medicines Agency (EMA) launched a stakeholder consultation on the revised 'European Commission guidelines on variations categories and procedures'. The Commission adopted a Delegated Regulation (EU) 2024/1701 on 11 March 2024 amending Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and its annexes (Variations Regulation) within the existing legal framework of Regulation (EC) No 726/2004 and Directive 2001/83/EC. As a follow up, the Commission is doing an initial review of the Guidelines on the details of the various categories of variations and the procedures (Variations Guidelines). The main changes proposed to the Introduction and Procedural section of the Variations Guidelines include the addition of procedural details on the

new/revised regulatory tools introduced with the Variations Regulation. ECHAMP submitted detailed comments considering that this opportunity to decrease unnecessary administrative burden for our industry was not sufficiently exploited in this proposal and that in some cases the proposal will even increase the level of categorization leading to time delays.

It is important to mention that a second revision of the variation framework is foreseen once the revision of the basic pharmaceutical legislation has been completed.

EMA and HMA launched a joint public consultation on European Medicines Agencies Network Strategy to 2028. The European Medicines Agencies Network is currently working to review and update its five year strategy. The updated strategy (**EMANS 2028**) addresses changes to the regulatory and technical landscape that have occurred more rapidly than first anticipated. While it is taken into account that the outcome of the revision of the pharmaceutical legislation cannot be preempted, it does prepare the network to be able to harness the opportunities provided by change. ECHAMP will continue to monitor the developments in particular the focus area on leveraging data.

EDQM & the European Pharmacopoeia

In December 2023, ECHAMP had the opportunity to exchange with the management of the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe. ECHAMP advocated for an update of the list of substances, so as to prioritise those which would be most beneficial for industry and the regulators. Therefore, ECHAMP followed up this year by sending a list of additional substances which reflect the current market relevance.

Consultations

ECHAMP welcomes the EDQM continuous efforts to integrate homoeopathic pharmaceutical standards in the European Pharmacopoeia Monographs:

- Pharmeuropa 36.4 draft monograph 2.8.25 'High-performance thin-layerchromatography of Herbal Products'
- Pharmaeuropa 36.4 draft monographs 'Methods of preparation of homoeopathic stocks and potentisation'
- Pharmeuropa 36.2 draft monographs 'Calendula for homoeopathic preparations' and 'Chamomilla for homoeopathic preparations'
- Pharmeuropa 36.1 draft monographs 'Magnesium phosphoricum for homoeopathic preparations'
- Pharmeuropa 36.1 draft monographs 'Cuprum metallicum for hom prep', 'Ferrum metallicum for hom prep', 'Cadmium sulfuricum for hom prep'.

EDQM – essential role for public health

In June, EDQM held a conference to mark its 60 years of existence around the theme 'Today, tomorrow, together for public health'. Numerous representatives from authorities, universities, associations – amongst which ECHAMP – and companies attended the event at Strasbourg. Renowned experts shared their perspectives in navigating public health challenges in 2024 and on the future of public health, the key trends and developments.

ECHAMP fully endorses the crucial role of EDQM in ensuring public health protection and appreciates the collaboration in achieving this shared goal.

← **Dr Petra Dörr at EDQM Conference to mark its 60 years of existence around the theme 'Today, tomorrow, together for public health'**

Global developments

World Health Organization (WHO)

In its 76th session in Geneva 21-30 May 2023, the World Health Assembly adopted a decision to develop a new global strategy on traditional medicine, 2025-2034.

As follow-up of this first WHO Summit, WHO released in April its draft traditional medicines strategy 2025-2034 for public consultation. The cornerstone of this strategy is that traditional and complementary medicine enjoys global demand and usage being present in all six regions of the world. ECHAMP responded to the consultation fully supporting WHO in its goal to quantify and qualify the contribution of Traditional, Complementary and Integrative Medicine (TCIM) to universal health. ECHAMP agrees that national frameworks and guiding policies are crucial for the positioning of TCIM within the overall health care landscape to facilitate access to quality, safe and effective TCIM.

We are very encouraged to see that the WHO secretariat will endeavour to develop and strengthen collaboration with partners, this collaboration will be key to the future success of the strategy. ECHAMP offered its extensive expertise on the European approach. ECHAMP will continue to follow the work of the WHO with special interest for the work of their committee on medicinal products.

Liga Medicorum Homeopathica Internationalis (LMHI)

LMHI organised a number of meetings with European stakeholders to exchange on the future of homeopathy from a global perspective and on how to preserve its legacy for the generations to come.

25 years of ECHAMP – behind its success

In 1999, ECHAMP was founded by 25 pioneering members with a shared vision to advance the interests of homeopathic and anthroposophic medicinal products (HAMP) across Europe. Through persistent and consistent advocacy, ECHAMP played a key role in ensuring that European institutions considered the unique characteristics of this industry when drafting Directive 2001/83/EC and its Annex I—an early and significant achievement.

In more recent years, a number of key achievements were made in advancing appropriate regulation for our products such as the official exemption from mandatory safety features, reflecting the specific nature of these medicine and the provisional exemption allowing the import of mercury for the production of homeopathic and anthroposophic medicinal products, ensuring the continued availability of essential substances for manufacturing. In 2018, ECHAMP hosted the 'EU Convergence – Technical Workshop on Quality Control Standards' in Strasbourg. This event brought together companies' experts from across the European industry to address key issues related to pharmacopoeial substance monograph standards. The outcome was a unified industry vision, which was then presented to the relevant competent authority.

Since its creation, ECHAMP also continued its engagement with regulatory bodies, participating in regular exchanges with HMPWG. Numerous industry dialogue meetings were organised, discussing developments in quality and safety standards in relation to our products. These efforts fostered a better mutual understanding between medicines agencies and the industry.

Throughout the past 25 years, ECHAMP also organised several events and conferences at the European Parliament raising awareness and presenting evidence and reinforcing the scientific credibility of homeopathic and anthroposophic medicine. One notable event was the presentation of ECHAMP's Availability Report in 2013, which highlighted the accessibility and regulatory challenges facing homeopathic and anthroposophic medicines across the EU.

Sector synergies

Over the years, ECHAMP has consistently supported exchange with sector stakeholders, leading to greater inclusion of Integrative Medicine into health systems.

In 2007, through this collaboration, ECHAMP successfully advocated for EU funding for Complementary and Alternative Medicine, which was later adopted as part of the EU's 7th Framework Programme for research and innovation. As a member of the CAMbrella Board of Experts, ECHAMP contributed to the presentation of the final project results, further advancing the understanding and development of CAM across Europe. This project culminated in the publication of the CAMbrella report in 2012.

In 2008, ECHAMP co-organized the inaugural EU Homeopathy Day alongside sector stakeholders, highlighting the importance of homeopathic medicine within the broader healthcare landscape. This successful event paved the way for many more in the following years.

In 2017, the European Parliament passed a resolution supporting patient access to complementary and alternative therapies and medicines, recognizing the value of CAM in healthcare. In 2021, the European Parliament Resolution on the pharmaceutical strategy for Europe officially acknowledged the benefits of integrative medicine, marking another step forward for HAMP advocacy. And in 2022, in a resolution on strengthening Europe's fight against cancer, the European Parliament recognized the role of integrative medicine, affirming the contributions of homeopathic and anthroposophic treatments in holistic care Team work.

From its founding in 1999 to its continued advocacy and achievements in 2024, ECHAMP has played a pivotal role in representing the interests of the manufacturers and distributors of homeopathic and anthroposophic medicinal products providing a platform to speak with one voice. ECHAMP advocated for and contributed to appropriate regulation, supported standards and requirements with the unified goal of patient access to high quality safe products across Europe.

None of this would have been possible without the continuous dedication of ECHAMP members' experts, the contributions of current and former Board of Management members, including successive Presidents, and the commitment of the ECHAMP team.

ECHAMP has played a pivotal role in representing the interests of the manufacturers and distributors of homeopathic and anthroposophic medicinal products for over a quarter of a century providing a platform to speak with one voice.

ECHAMP embarking on the next chapter

Reflecting on ECHAMP achievements, ECHAMP felt the need to update its strategy and to have a forward-looking perspective beyond the revision of pharmaceutical legislation. There is no doubt that the political and regulatory environment continues to be challenging. While the discussions were conducted with a reflective approach on how to continue to successfully navigate these challenging times, the focus was also on how to harness the opportunities provided by emerging trends in healthcare and the significant contributions our industry can make to the future. ECHAMP's strategic direction will prioritise the unique challenges faced by our sector; and legislative changes, such as the ongoing review of the Directive 2001/83/EC, remain the top priority.

At the Membership Assembly in November, the Members gave their full support to this renewed strategy and the new structure. The Members also elected a new Board of Management, with a high level of political, regulatory and legal expertise who will provide strategic direction aligned with the goals of our Association.

Board of management

Pilar Macías Fernández
(President)
Labo'life

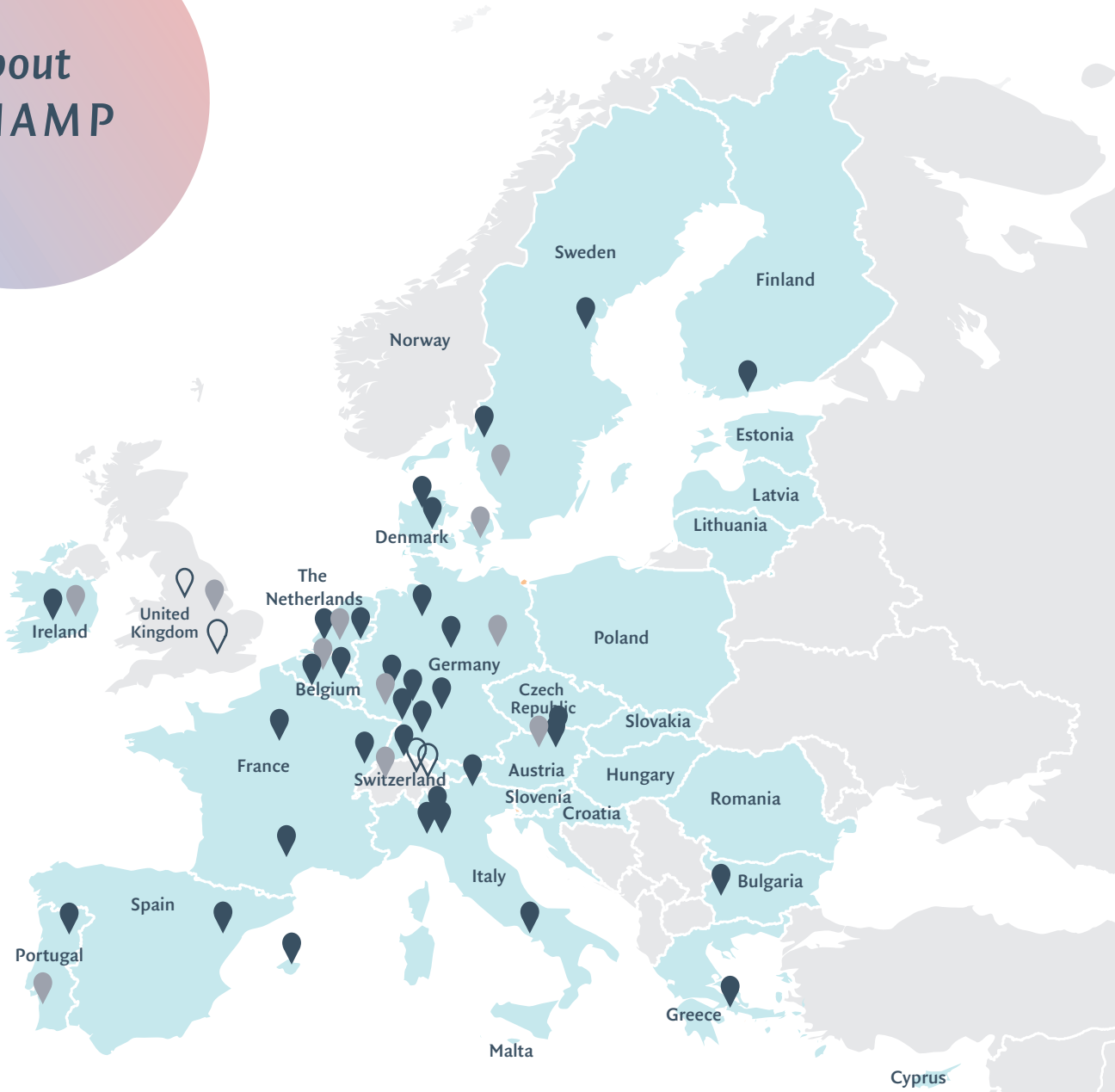
Christina Oehler
Wala

Dr Barbara Sterner
Weleda

Dr Paz Marta Diaz-Guardamino
Sanum-Kehlbeck

Dr Thor Kastilan
Dr. Reckeweg

About ECHAMP



29 Full Members from 14 EU Member States and 4 Extraordinary Members from Switzerland and UK

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

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