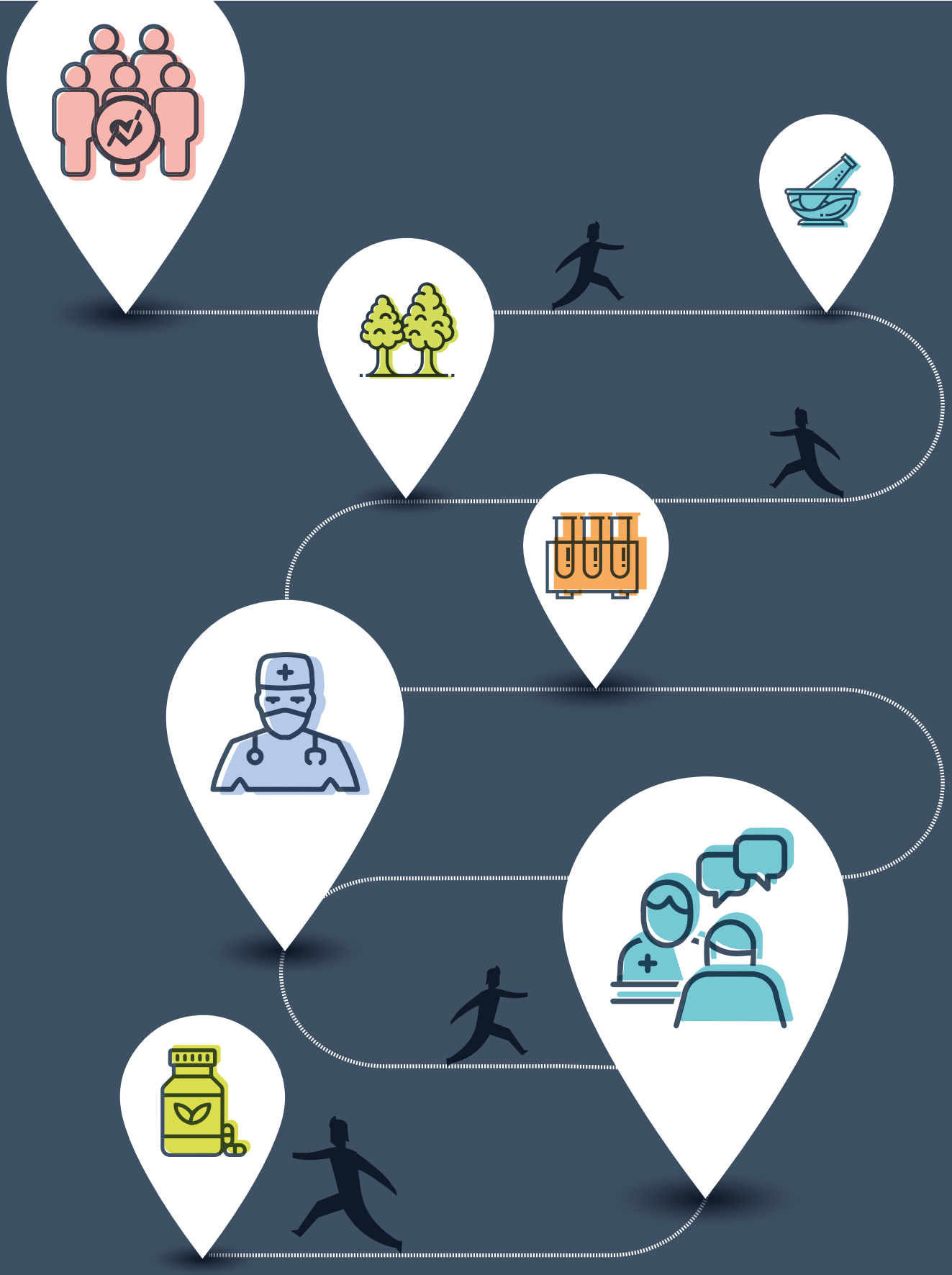


Annual Report 2020

ECHAMP

European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

Words from the President

2020: A year like no other

As 2021 gets underway, it is hard to imagine what the world will be like next month, let alone next year or ten years on.

The Covid-19 pandemic has left a lasting imprint on the world. There is no one who will not be affected in some way – it's not just the lives taken and livelihoods destroyed, but the long-term economic and social impact, reverberating throughout the globe and changing, within such a short space of time, the way we lead our lives, interact with one another, do business and manage our health. The fall-out of 2020 will determine a very different future for our children.

The pandemic gives us all the opportunity to reflect, assess, learn from the experience and look forward. This applies as much to our sector as to any other.

The EU responded quickly to this challenge, and its new Pharmaceutical Strategy, adopted on 25 November 2020 (→ *page 5*), seeks to remedy some of the weaknesses of the current system brought to light and reinforced by the pandemic. It aims to improve and accelerate patients' access to safe and affordable medicines, support innovation in the EU pharmaceutical industry, create a future proof regulatory framework and promote research and technologies that actually reach patients and fulfil their therapeutic needs. This strategy sets the context for legislative and non-legislative action over the current Commission term of office.

> **A truly holistic, patient-centred, forward-looking EU Pharmaceutical Strategy will combine the best of the established therapies with the new.**
>
> **David Reckeweg-Lecompte, President, ECHAMP**

ECHAMP believes that a forward-looking EU Pharmaceutical Strategy should balance curative treatments with preventive care, including appropriate self-medication, and that the industry for homeopathic and anthroposophic medicinal products has an important contribution to make in this respect.

The sector today

Homeopathy is the third most popular specific complementary medicine, used in 100 countries globally (*World Health Organisation*); homeopathic and anthroposophic medicinal products have long-standing use in most EU Member States and have been widely used in primary and clinical care across Europe for decades. More than one in five Europeans use homeopathy for their health care.

70% of users experience improvements in their health and patients express very high levels of satisfaction with these treatments. The growing use of these medicines is consistent with the trend towards integrative health care (→ *page 14*), which offers a multi-disciplinary approach requiring the application of the best options from both conventional and complementary and alternative medicine. They also offer a solution for self-management of minor health conditions, in line with the trend towards self-care.

Homeopathic medicinal products have a long-standing, solid legal framework in European pharmaceutical legislation, supported by high quality standards as defined in the European Pharmacopoeia. The current regulatory framework strikes a balance between ensuring the quality and safety of these products, and at the same time giving citizens access to the medicines of their choice.

This EU-based industry has been serving the European market for decades and the EU is the global centre of expertise in manufacturing, quality standards and regulation of this industry.

A roadmap for our sector

Homeopathic and anthroposophic medicinal products can make an important contribution to tackling the health challenges that Europe is now facing and the rising burden of diseases in the EU. They offer valuable treatment options alongside conventional medicine systems in support of EU health policy goals on multimorbidity, polypharmacy, chronic diseases and an ageing population. They can contribute to safe and effective strategies to reduce the use of antibiotics. A growing body of scientific research, including published clinical studies, demonstrates the effectiveness of these forms of treatment.

ECHAMP is more determined than ever before to play our part in meeting the expectations of the European patients and to ensure the availability of products needed for a broad choice of individually adapted health solutions.

In its 2018 report on access to medicines (2018/C 263/02), the European Parliament demands that patients 'have access to the healthcare and treatment options of their choice… including complementary and alternative therapies and medicines.' People across the EU expect to benefit from equal access to safe, state-of-the-art and affordable therapies – and this means both new and established therapies.

These medicines offer cost-effective options that contribute to the financial sustainability of healthcare systems. Their full potential must be further exploited, as must their contribution to reducing any unnecessary burden on health systems at a time when resources are already stretched.

A forward-looking, holistic, patient-centred strategy

A truly holistic, patient-centred, forward-looking EU Pharmaceutical Strategy will combine the best of the established therapies with the new. The conscious integration of pluralism into the EU healthcare system will ensure that patients and health professionals have access to a wide choice of reliable, safe and high-quality medicinal products, including homeopathic and anthroposophic medicines.

ECHAMP embraces 2021, more determined than ever before to play our part in meeting the expectations of European patients and to ensure the availability of products needed for a broad choice of individually adapted health solutions.

A roadmap for our sector: Strength in unity – resilience in diversity

A Pharmaceutical Strategy for Europe

2020 was marked with anticipation regarding the direction the new *Pharmaceutical Strategy for Europe* would take. Would the Covid-19 crisis, which had exposed the existing shortcomings of the current environment, spark rushed decisions on short-term solutions, or would the strategy continue to build on the current foundation? ECHAMP is pleased to see that the Commission's Pharmaceutical Strategy, published in November, acknowledges both the fact that the EU is starting from a strong foundation and the need for swift action. It argues that 'Europe has a comprehensive pharmaceuticals system, from the development and authorisation of medicines to their post-authorisation monitoring.'

The overall goal of the strategy is 'to help ensure Europe's supply of safe and affordable medicines to meet patients' needs.' This is based on the context that '…people across the EU expect to benefit from equal access to safe, state of the art and affordable new and established therapies.'

The strategy consists of both legislative and non-legislative proposals.

There is a legal obligation on the pharmaceutical industry to ensure that patients have access to and supply of medicines. We need to work closely and try to have a holistic pharmaceutical strategy, so as to be able to deliver what we need for patients.

Stella Kyriakides, European Commissioner for Health

ECHAMP response

ECHAMP voiced its support for this initiative in its response to the public consultation on the roadmap for the Pharmaceutical Strategy. We welcome the Commission's acknowledgement of the need to build a holistic, patient-centred, forward-looking pharmaceutical strategy. We endorse the issues identified as high priority – namely accessibility, affordability, availability, sustainability and the need to modernise the regulatory framework to be able to integrate technological and scientific advancements.

However, we also see the need for a note of caution when addressing legislative measures with respect to the current pharmaceutical Directive. It is vitally important not to jeopardise patient access to existing medicines.

There are specific elements in the strategy with which our sector can identify and to which we can give significant support in order to increase the vitality of EU health systems, examples being the management of various chronic diseases and the reduction of unnecessary antibiotic use.

In our response, we also reiterated the valuable role homeopathic medicinal products play alongside conventional medicines in tackling the unique health challenges that Europe is now facing. This role has become increasingly important, especially in the case of multimorbidity, polypharmacy, chronic diseases and an ageing population.

This is an opportunity for the full potential of our products to be exploited for the sake of the citizens of Europe and the sustainability of its health systems.

Our products have long-standing use in most EU Member States and have been widely used in primary and clinical care across Europe for decades, offering affordable solutions for (self-) management of minor health conditions.

We are an EU-based industry and the EU is the global centre of expertise in manufacture, safety and quality standards for these products. The high level of regulation ensures that patients have access to safe, good quality medicines of their choice.

A truly holistic patient-centred, forward looking pharmaceutical strategy will combine the best of the established therapies with the new. The conscious integration of pluralism into the EU healthcare system will ensure that patients and health professionals have access to a wide choice of reliable, safe and high quality medicinal products, including homeopathic and anthroposophic medicines.

This will require full recognition of the strength of diversity, not only in the need for a broad spectrum of products (including innovative products, generics, biosimilars and complementary medicines) to meet the expectations of Europe's patients, but also at the level of the division of competences and power between the EU and the Member States, allowing for different national traditions and long-standing use.

Next steps

The European Commission now has the task to take the EU, the best regulated market in the world, and elevate it to the next level, in order to reinforce the sector's global competitiveness, while at the same time continuing to meet patients' needs and expectations – leaving no one behind.

ECHAMP will follow the process with careful attention and will use this new opportunity to strive for the full potential of our products to be exploited for the sake of the citizens of Europe and the sustainability of its health systems.

A strong foundation in EU law

Specific legislation for homeopathic medicinal products has deep roots in their broad use in the Member States. Even before the introduction of the first EU legislation in 1992, homeopathic medicinal products were prescribed and used in all Member States. Regulation of these products dates back to 1967 in France and 1976 in Germany.

In 1992, Directive 92/73/EEC created specific provisions for homeopathic medicinal products with the intention of creating a legal frame that would allow patients access to the medicinal products of their choice, while at the same time making sure that all precautions would be taken to ensure their quality and safety. The basic values for the legislation were free trade within the Community and freedom of choice for patients and the main motivation behind the legislation was the intention to safeguard quality and safety.

Legislative Acts for Homeopathic Medicinal Products | **Regulatory Provisions** | **Regulatory Milestones** | **Institutional Reports**

EU Pharmaceutical Regulation 1992–2020: The milestones for homeopathic medicinal products (HMPs)

1992

Directive 92/73/EEC: defines HMPs and introduces optional rules for simplified registration (*Article 14*) and marketing authorisation (*Article 16*)

1995

EDQM: First monograph on homoeopathic preparations (European Pharmacopoeia)

1997

EDQM: First Homoeopathic Working Party

European Commission: Report on application of Directive 92/73 EEC (*Com (97) 362*)

European Parliament: Resolution on the status of non-conventional medicine (A4-0075/97)

European Parliament: Report (PE 227.183) on the Commission report on the application of Directive 92/73/EEC

1998

2001

Directive 2001/83/EC: integrates content of Directive 92/73/EEC

2002

European Pharmacopoeia: Separate chapter 'Homoeopathic Preparations' *(4th edition)*

EU Pharmaceutical Regulation 1992-2020: The milestones for homeopathic medicinal products (HMPs)

Legislative Acts for Homeopathic Medicinal Products

Regulatory Provisions

Regulatory Milestones

Institutional Reports

2003

Directive 2003/63/EC: Annex I includes chapter on quality and safety requirements for HMPs

2004

Directive 2004/27/EC: Simplified registration for HMPs mandatory in all Member States; Mutual Recognition Procedure / Decentralised Procedure for simplified registered HMPs

Homeopathic Medicinal Products Working Group (HMPWG) set up by Heads of Medicines Agencies

2006

EDQM: Homoeopathic Working Party split into Homoeopathic Manufacturing Methods (WP HMM) and Homoeopathic Raw Materials and Stocks (WP HOM) (monographs)

2009

Mutual Recognition Procedure: First procedure finalised in one Reference and two Concerned Member States

2010

Directive 2010/84/EU (pharmacovigilance): includes specific provisions for registered HMPs *(Article 14)*

2011

Decentralised Procedure: First procedure finalised in one Reference and four Concerned Member States

2015

European Commission: releases Matrix Insight Report on Availability of Medicines, including chapter on HMPs and anthroposophic medicinal products

2017

HMPWG: Report on the Regulatory Status of Homeopathic Medicinal Products for Human Use in EU And EFTA Countries

European Parliament: Resolution on EU options for improving access to medicines (2016/2057(INI)) calls for patient access to complementary and alternative therapies and medicines.

European Parliament: ENVI Committee study (PE 614.180) 'Complementary and alternative therapies for patients today and tomorrow'

2020

HMPWG : Questions and answers document on regulatory and legal issues concerning homeopathic medicinal products in the European framework

An appropriate regulatory environment

We welcome the initiative of the Pharmaceutical Strategy to simplify and streamline procedures and reduce costs, which would allow us to invest in the future of the sector.

ECHAMP works hard to ensure that the specificities of homeopathic and anthroposophic medicinal products are appropriately taken into account when it comes to new guidelines, such as those published by the European Medicines Agency (EMA) or the Heads of Medicines Agencies (HMA).

In regulatory practice, it can be observed that there is a tendency at national level that increasing amounts of data are requested for the registration dossier, which are relevant to prove Good Manufacturing Practice (GMP) compliance. In common with the whole pharma sector, our industry suffers from an increasing workload, especially as regards the lifecycle of existing products, and this applies all the more for this sector due to the very high number of products needed to properly sustain these types of treatments. We therefore welcome the initiative of the Pharmaceutical Strategy to 'simplify and streamline procedures and reduce costs,' which would allow us to invest in the future of the sector.

Safety

Homeopathic and anthroposophic medicinal products placed on the market must be safe. The safety of a medicinal product mainly depends on the amount of toxicologically relevant ingredients in the administered dose.

In 2020, the Homeopathic Medicinal Products Working Group (HMPWG) of the HMA published a consolidated list of ***First safe dilutions where homeopathic use is justified***. In principle, it is useful for the industry and for regulators to have a list of stocks with justified use and their 'finalised' first safe dilutions (FSDs), as this can decrease the level of documentation required for the registration dossier for those products with stocks which are less concentrated.

However, the way a first safe dilution is calculated includes many individual considerations, conditions and safety factors, so these listed FSDs cannot be considered as finite but only as the most conservative approach. As a stand-alone document, this new list may lead to misinterpretation, for example in the assessment of homeopathic medicinal products with a high concentration of an active substance by regulators not involved in the background reasoning for the calculation of the FSD. A new guidance document on non-clinical documentation recently published by HMPWG does not improve this. Proposals from industry associations and scientists for a more adequate calculation of acceptable amounts of toxicologically relevant ingredients have still to be taken into consideration.

A recent publication, ***Material Risks of Homeopathic Medicinal Products: Regulatory Frameworks, Results of Preclinical Toxicology, and Clinical Meta-Analyses and their Implications*** (*Habs and Koller, Complementary Research, 2020*) concludes that registered homeopathic products marketed in the EU are safe and explains how a toxicological assessment can be performed in an appropriate manner.

ECHAMP continues to hold the position that the evaluation criteria for FSDs should be based on a transparent assessment of scientific literature data. There is no reason to treat homeopathic medicinal products more strictly than other medicinal products.

Quality

At the end of 2019, HMPWG adopted a new ***Questions and Answers Document on the Quality of Homeopathic Medicinal Products*** (Q3), the requirements of which, in ECHAMP's view, mainly increase the administrative burden without showing any added value for the quality or safety of the products.

According to that document, changes in the suppliers of raw materials used for the production of active substances (e.g. mother tinctures or dilutions thereof) for authorised homeopathic medicinal products are required to be notified through the procedures for variations. This significantly restricts the flexibility of choice of raw material suppliers. Such flexibility is essential due to the high number of substances required for the full range of medicines needed for the comprehensive practice of homeopathic therapy.

It is especially critical for fresh plant material with an inherent time constraint to enter into the production process.

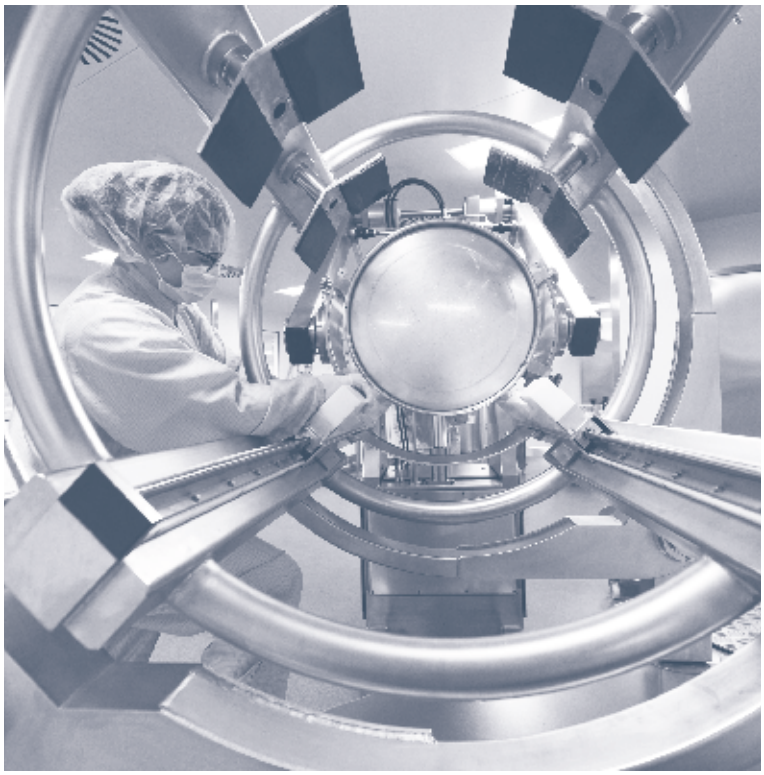
ECHAMP's position on this matter is that a sufficient level of safety is already guaranteed without this additional administrative requirement, as all raw material suppliers are known and qualified by the manufacturers according to internal company quality management systems, in their turn regularly assessed by GMP inspectors. This requirement is an example of the trend for an increasing number of GMP-related topics to be discussed in the regulatory environment and of the lack of efficiency in the management of the product lifecycle.

ISO standards for the identification of a medicinal product

The EMA is in the process of implementing the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP).

ECHAMP continues its work with the EMA IDMP task force on substance, product, organisation and referential master data (IDMP/SPOR). After two rounds of comments, the task force plans to release the second version of the Product Management Services (PMS) EU Implementation Guide early in 2021, at which point the deadlines for the transition phases for the introduction of PMS will start. Work is currently underway on individual medicinal products with chemically defined constituents. The more complex products (and thus also homeopathic and anthroposophic medicinal products) will follow in the next phases. The ECHAMP working group was asked to participate in these next steps concerning this group of products. The realisation of the ISO IDMP will also result in an increased workload for the homeopathic industry.

The effort that is being put into developing the IDMP/SPOR will only be justified if dossier and variation requirements are adapted to this digitalisation, so as to enhance regulatory efficiency. As a matter of principle, duplication of information should be avoided and variations of these standard data sets should be possible in a lean, digital manner without resource intensive dossier management. We trust that the Pharmaceutical Strategy will deliver on its intention to optimise the regulatory environment, enabling innovation and digital transformation and securing the future of the EU-based pharmaceutical industry.



The European Pharmacopoeia: High quality standards for homeopathic medicinal products

The European Pharmacopoeia standards are making an essential contribution to the growing field of integrative medicine.

The European Pharmacopoeia standards are making an essential contribution to the growing field of integrative medicine.

The experience of the Covid-19 pandemic has highlighted the need to include a wide range of elements in the EU Pharmaceutical Strategy (→ *page 5*). It must of course incorporate elements such as the global availability of medicines and the need for fast track registration for life-saving medicines; at the same time, however, it should also include a strategy for an integrative approach to healthcare that supports and enhances conventional medicine with other measures (→ *page 14*). Integrative medicine combines a wide range of high quality medicines, including both conventional and traditional medicines, and these should be available all over the world.

It has become increasingly important to think both globally and integratively.

In this context, the European Directorate for the Quality of Medicines (EDQM) plays a central and ever more important role in continuing to set high quality standards for all medicinal products.

In its conference in June, *EDQM & European Pharmacopoeia: State-of-the-art Science for Tomorrow's Medicines*, EDQM highlighted the increasing importance of cooperation between the world pharmacopoeias as standard setters. Harmonisation and legal recognition are central goals between the different pharmacopoeias. EDQM emphasised the importance of modern analytical methods, data exchange and incorporation of new technologies. It was also apparent, that in some parts of the world, such as in Central and South America (e.g. Mexico and Brazil) and in India, herbal medicines and homeopathic medicinal products are an important part of their medical tradition. In these countries, this is well reflected in the pharmacopoeia standards.

ECHAMP supports the position of Susanne Keitel, Director of EDQM, which takes its lead from the European Council, that access to good quality medicines and health care systems is a basic human right.

Looking at the complex supply chains and the increasing exchange of data we are facing, it has become essential to intensify this international work, as EDQM has been doing for years.

ECHAMP is very aware of the changing global context and follows the work of EDQM with careful attention, sending expert comments to EDQM drafts. The Monograph on *Methods of Preparation of Homoeopathic Stocks and Potentisation* is a critical and well-written technical piece in the puzzle of the legislative frame for our sector. ECHAMP's member companies provide valuable input to the further development of that basic European Pharmacopoeia (Ph.Eur.) monograph whenever changes are proposed.

The commitment to setting quality standards for homeopathic manufacturing methods and preparations, and the harmonisation and legal recognition that ensue, are essential to the future of our industry, enabling the availability of high quality, affordable medicine throughout the world.

We appreciate and continue to support the efforts made in that direction by the European Pharmacopoeia.

A global context – Integrative medicine

In 2020, some specific events highlighted the growing trend towards integrative medicine in Europe and around the world. Integrative medicine combines conventional and complementary medicine into an overall concept focusing on the whole person, allowing patients to access a broad choice of individually adapted solutions. This trend is endorsed around the globe by prescribers, patients and health authorities.

One in two EU citizens uses complementary medicine integrated with conventional care. Integrative medicine combines a wide range of high quality medicines, including both conventional and traditional medicines.

Sirpa Pietikäinen MEP

The World Health Organization (WHO) ***Global report on Traditional and Complementary Medicine 2019*** reports that homeopathy is used in 100 countries around the world, making it the third most popular specific complementary medicine after acupuncture and herbal medicine. Thousands of doctors with experience in homeopathic medicine successfully treat patients in an integrative fashion.

Homeopathic and anthroposophic medicinal products meet society's need both for affordable medicines with long-standing use and for medicines which are safe and do not negatively affect our environment. In times where antibiotic resistance is a real issue and where oncology and mental health are high ranking topics in society, integrative health systems can make a valuable contribution in responding to today's needs

European Parliament Interest Group on Integrative Medicine & Health

The European Parliament Interest Group on Integrative Medicine & Health brings together Members of the European Parliament (MEPs) to promote these issues in European Parliament public health policy. Its launch event, organised by EUROCAM (the European platform for organisations representing patients, medical doctors, veterinarians and practitioners in the Complementary and Alternative Medicine sector), took place online in December, hosted by MEPs Sirpa Pietikäinen, Michèle Rivasi, Tilly Metz, Eleonora Evi, and Margrete Auken and chaired by Sirpa Pietikäinen.

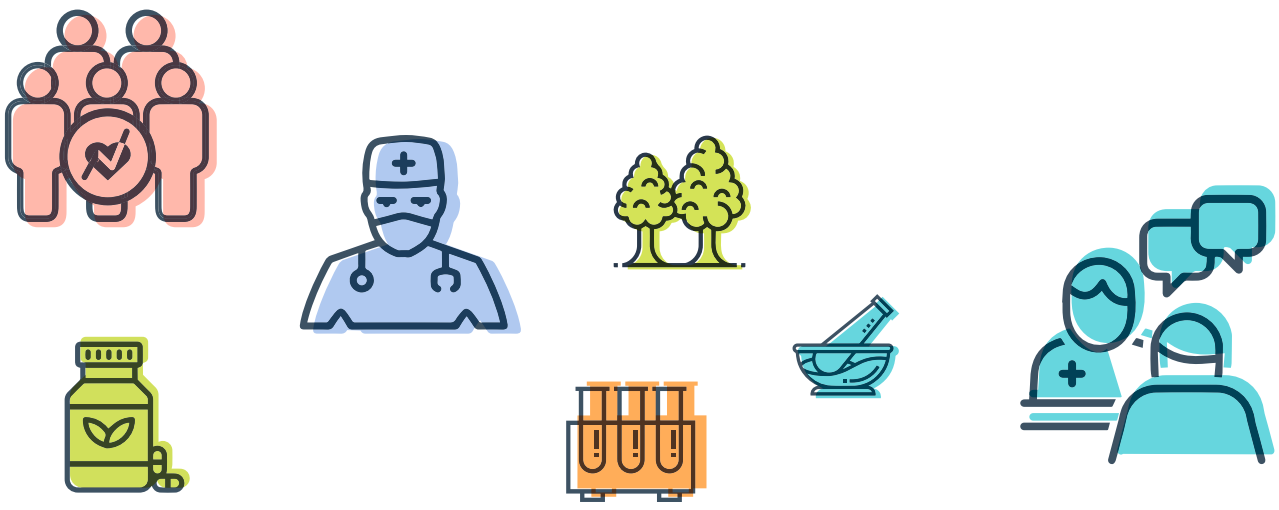
The inclusive approach of integrative medicine meets the demand of EU citizens for a holistic, patient-centred approach in medicine. Speakers showed how it has a significant contribution to make to the contemporary challenges of antimicrobial resistance, the increasing prevalence of non-communicable diseases, soaring healthcare costs, and the aftermath of the Covid-19 pandemic.

Bavarian department deals with integrative medicine

The state of Bavaria in South East Germany has established a new department within its Ministry of Health with a focus on integrative medicine, committing to the establishment of a Chair in Integrative Health at a university in Bavaria. In so doing, it follows the lead of Baden-Württemberg and both states come in line with the governments of India and Switzerland, with government departments responsible for an integrative approach to healthcare.

IVAA – one hundred years of anthroposophic medicine

2020 marked the first centenary of anthroposophic medicine, celebrated by the International Federation of Anthroposophic Medical Associations (IVAA) with a live-streamed symposium, 'Teaming up Against Cancer.' The aim was to contribute to the current debate on how to support patients with cancer across all EU Member States. Anthroposophic medicine has a long tradition in providing integrative cancer care, which combines state-of-the-art conventional oncology with an individualised approach addressing the patient's physical, mental and spiritual needs. An example from the German State of Baden-Württemberg, the Competence Network on Integrative Medicine, could provide a blue-print for what could be done at European level.



Inside ECHAMP

The whole world will look back on 2020 as an unusual working experience.

As members of a European association, colleagues at ECHAMP are used to remote working via email and conference call. But, in line with the rest of the world, 2020 took these working methods to an extreme.

Despite the challenges, ECHAMP Board members continued to meet and collaborate as usual. Board meetings and even the annual Membership Assembly were held on line.

Two specialist webinars were held for regulatory affairs colleagues, addressing the current quality and safety issues they faced in their everyday work. The second session was dedicated to the EMA database and the upcoming IDMP/SPOR system (→ *page 11*). The Members appreciated the opportunity to exchange knowledge and debate concepts; two further online sessions are planned in 2021.

ECHAMP now has 37 Full Members from 14 EU Member States, plus Norway. As a result of the UK leaving the EU, the British members have become Extraordinary Members, which means we now have four in total, two from Switzerland and two from UK.

There are 11 Associated Partners, the national manufacturers' organisations.

We continue to build and strengthen relationships within our sector, including with the European patient, practitioner and doctor associations, EUROCAM (the European platform for organisations representing patients, medical doctors, veterinarians and practitioners in the Complementary and Alternative Medicine sector) and the national industry associations.

Board of Management of ECHAMP

About 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.

37 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 Member of ECHAMP

Click on each flag to direct you to a Member's website

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