Homeopathic and Anthroposophic Medicinal Products in the EU

Spotlight on an Industry



European Coalition on Homeopathic & Anthroposophic Medicinal Products

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Foreword

I am very happy to introduce this publication from ECHAMP, which is an authoritative source of information on the sector for homeopathy and anthroposophic medicine in the EU.

Homeopathic and anthroposophic medicinal products have been safely on the market in Europe for many decades. These long-established therapies and their products are used in primary and clinical care across Europe and offer valuable treatment options in support of EU health policy goals. Europe is a global centre of expertise for this industry and there is a strong foundation for these products in European law. Legislation for homeopathic medicinal products has deep roots in their broad use in the Member States.

This publication confirms the long-established use, the very high safety profile, the high level of patient satisfaction and the emerging evidence base for the effectiveness of these medicines. It presents a unique picture of the real world context for this sector with up-to-date data on the industry, outlining the added value these therapies offer to society in terms of safety, effectiveness, cost-effectiveness and the environment. It is the only such source for summarised EU data on this sector.

As a long-time attentive user and observer of homeopathic medicines, I have direct personal experience of the important role these therapies play within complementary and integrative medicine. I am committed to ensuring that they take their rightful place within European health care.

Michèle Rivasi Member of the European Parliament

Executive summary

Homeopathy and anthroposophic medicine can make an important contribution to society. Studies show that these long-established and popular therapies and their medicinal products have a role to play in the face of major health challenges in the European Union (EU) – for example, in fields of specific relevance to EU health policy such as antimicrobial resistance, polypharmacy, chronic diseases and healthy ageing. In addition, they offer clinical effectiveness in certain contexts, low incidence of side effects and cost-effectiveness.

These are long-established European medical traditions, with Europe the global centre of expertise for homeopathic and anthroposophic medicinal products. Millions of European citizens choose to use them for their health care. Growing demand for these products is met by an industry characterised by unique levels of variety and complexity.

There is significant to high demand for homeopathic and anthroposophic medicinal products in at least two thirds of EU Member States, some with and some without a long-term tradition. Market studies and other data confirm high levels of awareness of homeopathy and anthroposophic medicine in many countries, with growing use of and demand for these medicines and positive attitudes of citizens towards these therapies. Patients choose these products for their high safety profile. Users tend to be female with higher levels of education; patient satisfaction is generally high. Nevertheless, citizens express a wish for more support regarding complementary medicine from medical professionals. They need and want easily accessible and trustworthy information that can support informed decisions on treatment options.

The sector requires sophisticated expertise to meet complex quality requirements. Prescribers need 3,000 distinct source materials for the proper practice of these therapies and some larger manufacturers source as many as 2,000 starting materials, mostly of botanical origin, from over 100 different suppliers. ECHAMP member companies manufacture 1.5 million distinct finished products, with different potencies and dosage forms, in big, medium, small and very small batches. The sector produces 200 million units of finished products each year. ECHAMP members balance a significant proportion of non- or low-profit products within their business models.

Pharmacies remain the main channel for the distribution and sale of these products. E-commerce is growing, generally carried out by pharmacies.

A review of research in this field demonstrates the important role these therapies and their products can play in helping to meet some of the major health challenges of our times.

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Introduction

This report provides an up-to-date profile of the sector for homeopathic and anthroposophic medicinal products in the EU, outlining the demand for these medicinal products in the EU, presenting the characteristics of this industry and summarising the evidence base that underpins their use in health care. It is the only comprehensive review of this sector.

Data is drawn from a number of sources: publicly available statistics and data, market studies, social barometers, published and peer-reviewed research, data from ECHAMP partners and other stakeholders, and two detailed surveys of ECHAMP Full Members (2015 and 2018), the companies who manufacture and distribute these products in the EU.

Chapter 1 profiles the demand for homeopathic and anthroposophic medicinal products in the different EU markets in a variety of ways, summarising data from in-market studies and other data to quantify and profile users, their choices and their needs; Chapter 2 presents a detailed profile of the industry and its manufacturing processes; and Chapter 3 demonstrates the value that homeopathy and anthroposophic medicine and their medicinal products can bring to health care in the EU, in terms of clinical effectiveness, safety and cost-effectiveness, with full reference to quality published and peer-reviewed studies and research.

This is an established and growing EU-based industry with a unique profile. It offers significant benefit and service to millions of European citizens and has a valuable contribution to make to healthcare systems and Europe-wide health policy challenges.



Chapter 1

The demand for homeopathic and anthroposophic medicinal products

Historic data and recent analysis demonstrate a significant to high demand for homeopathic and anthroposophic medicinal products in two thirds of EU Member States, from Eastern, Central and Western Europe, some with and some without a long-term tradition. This chapter quantifies the demand for these products in EU markets in a variety of ways and summarises market studies and other data to quantify and profile users.

1.1 Sales per head in the EU

A comparison of sales per head of the population by market in the EU gives an indicator of relative demand for homeopathic and anthroposophic medicinal products (HAMPs). To ensure consistency, the data are adjusted to reflect national economic parameters: Gross Domestic Product (GDP) and Purchasing Power Standard (PPS). Figure 1 shows the adjusted sales of HAMPs per inhabitant (2013).

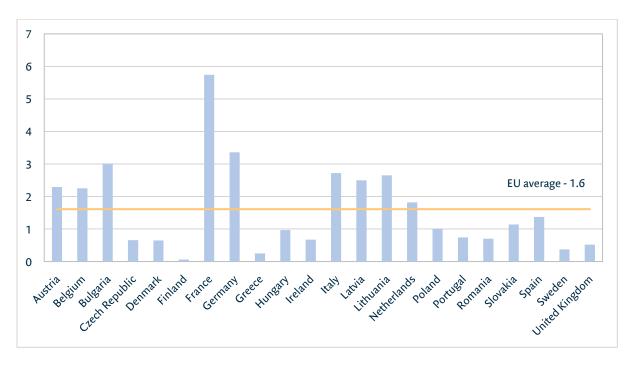


Figure 1: Sales of HAMPs per inhabitant in relation to GDP per capita in PPS (ex-factory 2013) (€)

¹ Homeopathic and Anthroposophic Medicinal Products in the EU – Profile of an Industry, ECHAMP 2015

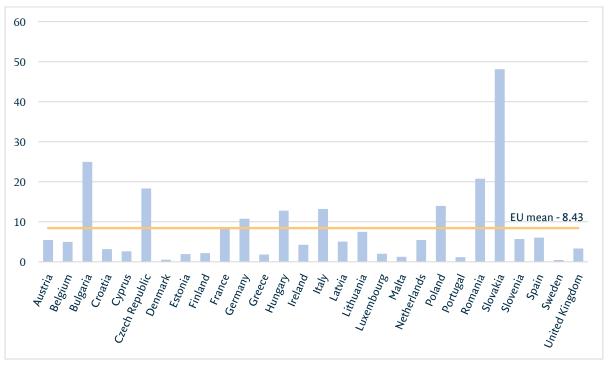
In 2013, eight Member States experienced adjusted sales clearly higher than the European average: France, Germany, Bulgaria, Italy, Lithuania, Latvia, Austria and Belgium. These numbers demonstrate a clearly visible demand for HAMPs supported by availability of the products.

A further four countries show adjusted sales of HAMPs per inhabitant at approximately the European average: Netherlands, Spain, Slovakia and Poland. These figures demonstrate some demand by the population in these countries, matched by a level of availability of the products.

1.2 Prescribers as an indicator of demand

Figure 2 illustrates the number of homeopathic prescribers² in the Member States in relation to the respective population numbers (see Annex I: Prescribers of HAMPs in the EU).

There are 8.4 homeopathic prescribers per 100,000 inhabitants in the EU. Countries with significantly higher than average prescribers per head include Bulgaria, Czech Republic, Romania and Slovakia, while France, Germany, Hungary, Italy, Lithuania and Poland are around the average.



Source: ECHAMP 2018

Figure 2: Homeopathic prescribers per 100,000 inhabitants (2018)

Actual numbers of prescribers have stayed more or less level since 2013. The number of homeopathic prescribers represents 2.5% of the total number of practising doctors in the EU,³ of which there is an average of about 356 practising doctors per 100,000 inhabitants.

² 'Homeopathic prescribers' equals the sum of homeopathic doctors plus homeopathic practitioners (see Annex I)

³ ECHAMP calculation - ECHAMP 2018, OECD 2015, EU 2016 (see Annex I)

In Bulgaria, Czech Republic, Hungary, Italy, Poland, Romania and particularly in Slovakia, the ratio between homeopathic prescribers and doctors per 100,000 inhabitants is higher than average, suggesting a higher than average demand for homeopathic medicine in these countries. By contrast, the ratio in the two largest markets, France and Germany, is around the average.

Meanwhile, the number of anthroposophic doctors per 100,000 inhabitants has remained mostly stable for the past few years (see Annex I).

In 2016, a new standard was approved by the Member States of the European Committee for Standardization (CEN) for the minimum requirements of health care provision by medical doctors with additional qualification in homeopathy and standardisation of specifications of their services. This is an important recognition of professional standards in this sector. Progress in implementation is being made in a number of countries.

1.3 Who uses homeopathy and anthroposophic medicine and why?

1.3.1 User awareness and use of HAMPs

A 1998 European Commission report4 informs that three out of four Europeans know about homeopathy, and of these, 29% use it for their health care – that was 100 million European citizens who used homeopathic medicinal products in 1998 in EU 15.

More recent data^{5,6} confirm that 7.6% of the EU population (38.6 m citizens) have used homeopathy in the past 12 months. Countries with the highest absolute number of users are France (13%), Germany (12%) and Italy (17%), while numbers from Austria (11%), Belgium (7%) and Lithuania (7%) confirm that an average or above average proportion of the population in those countries has also used homeopathy in the past 12 months. These numbers are generally lower than the findings of specific in-market surveys, as detailed in the following text.

Market data and social barometers demonstrate growing use of homeopathy and anthroposophic medicine across the EU. Market research figures confirm high awareness and a positive attitude of citizens towards these therapies:

- 94% of Germans have heard about homeopathic medicines⁷ and 56% have used them;⁸
- More than 80% of Italians know of homeopathy and 16% of the total population uses it at least once a year. Those who use homeopathy have been doing so for an average of 6.5 years. In

⁴Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74, Com (97) 362 final

⁵ ECHAMP 2018 extrapolated from ESS 2014 survey

⁶ EMG Acqua, 2016, 2018

⁷ Allensbach, 2014

⁸ Kantar TNS, 2018

⁹ EMG Acqua, 2016, 2018

- general these medicines are used more frequently than before, with a growth in use of 3%. 35% of the Italian population has a positive attitude towards homeopathy;¹⁰
- 69% of **French** people trust homeopathy¹¹ and one in five express total confidence in these products. 77% of respondents trust homeopathy as much as they trust analgesics,¹² compared to only 68% who trust antibiotics or antidepressants. 77% have used homeopathy, the majority (58%) several times and nearly all (87%) say their close family or friends have used homeopathy. Over 40% of French people have been using homeopathy for more than 10 years;¹³
- 69% of **Belgian** households use homeopathic medicines, ¹⁴ up from 50% in 2011. Among non-users of homeopathy, 70% state that they would like to use homeopathy in the future;
- 66.5% of **Spanish** citizens have heard of homeopathy, ¹⁵ 33% have used it, and 27% use it occasionally or regularly; ¹⁶ however a different study shows as few as 5% having used it in the past 12 months; ¹⁷
- 62% of **Austrians**¹⁸ have used homeopathic medicines, up from 50% in 2010, ¹⁹ when users included 62% of women and 37% of men, and about 60% of families with young and school-age children;
- 80% of the British population are aware of homeopathy, and 15% have used it;²⁰
- In Switzerland, 23% of doctors in outpatient care prescribe homeopathy at least once a year;²¹
- 91% of respondents in **Lithuania** are familiar with homeopathy and 66% use homeopathic medicinal products;²²
- A similarly high number of respondents in **Latvia** indicated they are familiar with homeopathy, ²³ with 63% indicating they use the products.

1.3.2 Why homeopathic and anthroposophic medicinal products?

Results of market and social data studies also show why users choose homeopathic medicines:

- 78% of **Germans** who use homeopathy do so because it has barely any side effects, 63% say it is well-tolerated and 58% that is well suited to children;²⁴

¹⁰ Doxapharma, 2012

¹¹ Ipsos, prepared for Les Entreprises du Médicament (leem). 'Observatoire Sociétal du medicament', 8ème vague, 2018

¹² Boiron IPSOS, 2012

¹³ Les Français et l'homéopathie, Ipsos, November 2018

¹⁴ Boiron, 2013

¹⁵ Sociodemographic profile of the homeopathy user in Spain, Atención Primaria, 2018

¹⁶ Estudio sobre conocimiento y uso de homeopatía en España, Revista Medica de Homeopatía, 2012

¹⁷ Sociodemographic profile of the homeopathy user in Spain, Atención Primaria, 2018

¹⁸ GfK, Homöopathie und pflanzliche Arzneimittel, Umfrage im Auftrag der Dr. Peithner KG, 2018

¹⁹ Homöopathische Einzelmittel werden statistisch nicht erfasst, IMS Health Austria, 2010

²⁰ British Homeopathic Association, 2015

²¹ Markun et al, Beliefs, endorsement and application of homeopathy disclosed: a survey among ambulatory care physicians, Swiss Med Wkly., 2017

²² User survey, Mitela, 2018

²³ User survey, Mitela, 2018

²⁴ Allensbach, 2014

- 53% of Italian users do so because it is natural and non-toxic;²⁵ Italians choose homeopathic medicines for their lack of side effects and contraindications (18%), because they are non-toxic (15%) or because they are perceived to be particularly suitable for less severe disorders such as anxiety, stress, cystitis and gastritis (12%).26 Homeopathic medicines are most frequently used for rhinitis, colds and flus (64%), joint or muscle pain (30%), allergies and respiratory problems (22%). The most popular medicine is arnica, used by 14% of Italians. Almost three out of ten Italians use them for children, especially for respiratory infections;
- 57% of Belgian users choose homeopathy because it is natural and 41% do so to avoid chemical medicines;27
- Nearly half of **Spanish** users of homeopathy do so to help them to help them have a healthy and balanced life (47.5%).²⁸ Others choose homeopathy because of the absence of side effects, its effectiveness and safety during pregnancy;29
- 39% of French users of homeopathic medicines choose these products because they are natural and have no side effects; 19% say they choose them because they work;³⁰
- 91% of Austrian users believe that homeopathic medicines have fewer side effects;³¹
- Users in Lithuania³² choose homeopathy because it is natural, safe, effective, gentle and has no side effects;
- Users in Latvia³³ choose it because the products are natural and effective and have no side effects.

Other research studies also confirm that users are attracted to homeopathy by its effectiveness and safe profile, 34 its natural characteristics, and to avoid the adverse side effects of chemical products. 35

15% of paediatric prescriptions in six countries (Germany, Russia, Bulgaria, Spain, Colombia and Israel) are for homeopathic preparations. Homeopathic preparations are more frequently used in upper respiratory tract infections, infant colic, sleep disturbances, and recurrent infections. In the majority of cases, they are used together with conventional medicines. The interest of physicians in using homeopathic preparations in children is in most cases driven by request of the parents.³⁶

1.3.3 Portrait of frequent users

Market and social data studies show that users tend to be mostly female, with a higher level of education and from the higher income brackets:

²⁵ Doxapharma, 2012

²⁶ EMG Acqua, 2016

²⁷ Boiron, 2013

²⁸ Sociodemographic profile of the homeopathy user in Spain, Atención Primaria, 2018

²⁹ Estudio sobre conocimiento y uso de homeopatía en España, Revista Medica de Homeopatía, 2012

³⁰ Boiron Ipsos, 2012

³¹ GfK, Homöopathie und pflanzliche Arzneimittel, Umfrage im Auftrag der Dr. Peithner KG, 2018

³² User survey, Mitela, 2018

³³ User survey, Mitela, 2018

³⁴ Sharples F, van Haselen R. Patients' perspectives on using a complementary medicine approach to their health. A survey at the Royal London Homoeopathic Hospital NHS Trust, London, 1998

³⁵ Patient satisfaction and side effects in primary care: An observational study comparing homeopathy and conventional medicine, Marian et al, BMC Complementary and Alternative Medicine, 2008

³⁶ Global Pediatric Health, 2016

- in **Germany**, 73% of women have used homeopathy and 48% of men;³⁷ users tend to be female, with high school level education and suffering from fibromyalgia or subthreshold depression; they also tend to abstain from eating fast food;³⁸
- in **Italy** 69% of users of homeopathic medicines are women, mostly aged between 35 and 54. More than half (51%) have a higher education. Those who live in North West Italy are the highest users of homeopathic medicines (30%) followed by the North East (28%);³⁹
- in France, 46% of women have used homeopathy in the past 12 months and 23% of men;⁴⁰ patients who choose homeopathy have higher education and markedly healthier lifestyle than people who opt for traditional medicine. They do not differ greatly in their health status or quality of life but exhibit large differences in their beliefs in holistic medicine and natural treatments, and in their attitude toward participating to their own care;⁴¹
- in **Spain**, typical homeopathy consumers are women (66%) with an average age of 46; 63% have higher education or professional training;⁴²
- In **Lithuania**, 97% of people purchasing homeopathic medicinal products are women;⁴³ the largest age group is aged 51-60, followed by the 21-30 year olds; higher education is an indicator of level of interest;
- 62% of those who buy the products in Latvia have the highest level of education. 44

Research⁴⁵ reports that users of homeopathic medicine are more likely to be female (75% women versus 25% men). They are also younger (average 47 years old versus 54 years old in the conventional medicine group) and have a higher educational status (32% college or university degrees versus 25%). In addition, they suffer more often from chronic diseases (60% versus 20%) and have severe health problems more frequently (23% versus 20%).

Another study confirms that patients of homeopathic primary care by physicians tend to be slightly more often female and have higher education than those of conventional primary care by physicians. Most of them have healthier lifestyles and a higher belief in holistic and natural treatments and are more likely to participate actively in their own care.⁴⁶

³⁷ Allensbach, 2014

³⁸ Characteristics of Homeopathy Users among Internal Medicine Patients in Germany, Complementary Medicine Research, 2016

³⁹ EMG Acqua, 2018

⁴⁰ Boiron Ipsos, 2012

⁴¹ Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine, 2014

⁴² Sociodemographic profile of the homeopathy user in Spain, Atención Primaria, 2018

⁴³ User survey, Mitela, 2018

⁴⁴ User survey, Mitela, 2018

⁴⁵ Patient satisfaction and side effects in primary care: An observational study comparing homeopathy and conventional medicine, Marian et al, BMC Complementary and Alternative Medicine, 2008

⁴⁶ Lert F et al., Characteristics of patients consulting their regular primary care physician according to their prescribing preferences for homeopathy and complementary medicine. Hom 2014:103, 51-57

1.3.4 Patient satisfaction

A number of studies demonstrate a high level of patient satisfaction with homeopathic and anthroposophic medicine treatment. Patient satisfaction with anthroposophic healthcare is shown to be generally high and therapeutic expectations are fulfilled.

Specifically:

- One observational study⁴⁷ of patients receiving homeopathic treatment confirmed that 95% of patients expressed very high satisfaction with their homeopathic treatment while rating of their previous treatment was only 20%; the large majority (89%) said homeopathy had improved their physical condition; compared to previous conventional treatment, patients reported that consultations cost less;
- Another study showed that patients of homeopathic physicians were more often 'completely satisfied' with their treatment than those in conventional care in a primary care setting - that is 53% compared to 43%;⁴⁸
- An observational study at Bristol Homeopathic Hospital over a 6-year period found that 70% of follow-up patients reported improved health, 50% referring to major improvement;⁴⁹
- Similarly, in a recent survey of patients in anthroposophic primary care practices, 50 patients report very high satisfaction with anthroposophic healthcare; patient satisfaction is generally high and therapeutic expectations are fulfilled.

In addition, market surveys show

- In Germany, 50% of internal medicine patients who have used homeopathy for their primary medical complaint reported perceived benefits.⁵¹ 70% of users are satisfied or very satisfied with effectiveness and lack of side effects;52 more than 70% thought that insurance companies should reimburse the costs; users of homeopathy are more likely to go to a pharmacy for treatment for everyday complaints than non users, and less likely to go to the doctor;⁵³
- French users of these products have a high level of confidence in the effectiveness of these medicines – 72% say they experienced positive benefits when they last used the products and 74% consider these products to be effective. 70% of French would use homeopathy as a first treatment solution and half have used homeopathy as a more serious treatment over a longer period. A similar proportion believe that homeopathic medicines should be offered to patients alongside conventional medicine and 83% support the right of doctors to prescribe homeopathy alongside

⁴⁷ An observational study of patients receiving homeopathic treatment, Van Wassenhoven M. and Ives G., 2004

⁴⁸ Patient satisfaction and side effects in primary care: An observational study comparing homeopathy and conventional medicine, Biomedcentral, 2008

⁴⁹ Spence et al., Homeopathic treatment for chronic disease: a 6-year university-hospital outpatient observational study. Journal of Alternative and Complementary Medicine, 2005

⁵⁰ Kienle et al., Anthroposophic Medicine: An Integrative Medical System Originating in Europe, Global Advances in Health and Medicine, 2013

⁵¹ Characteristics of Homeopathy Users among Internal Medicine Patients in Germany, Complementary Medicine Research,

⁵² BPI Forsa Umfrage, 2017

⁵³ Kantar TNS, 2018

conventional treatment in certain cases. A considerable proportion of French people (74%) are opposed to the proposal to discontinue the reimbursement of these products; half of all French are completely opposed to it;⁵⁴

- Eight out of ten (82%) **Spanish** people using homeopathy are satisfied or very satisfied with the outcome of their treatments, and this figure goes up to 99% in regular users.⁵⁵ Users of homeopathic products go to the doctor less frequently (8%) than the general population (18%);⁵⁶
- In **Italy**, only 19% of respondents⁵⁷ think that homeopathy is less effective than traditional medicine;
- 72% of Austrian users of homeopathic medicines find them effective. 58

1.4 Need for information

Citizens express a wish for more support and information regarding complementary and alternative medicine (CAM) from medical professionals. They need and want easily accessible and trustworthy information that can support an informed decision about treatment options.⁵⁹

1.4.1 How are users introduced to homeopathy?

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. Studies show:

- 67% of Germans try homeopathy on the recommendation of a friend or family member, 53% on the recommendation of a doctor or practitioner and about a third (37%) on the recommendation of a pharmacist;⁶⁰ 64% think it is important or very important for their doctor to be able to recommend homeopathy or natural medicines and 66% want to be able to purchase both natural medicine and homeopathy alongside conventional products in the pharmacy;⁶¹
- In Italy, 28% of users were introduced to homeopathy by a pharmacist; others were introduced by family and friends (39%), their general practitioner (20%), with recommendations from pharmacists and doctors on the increase.⁶² 41% go to their pharmacist for information on homeopathic medicines, while 35% expect their general practitioners to provide information on homeopathy;⁶³

⁵⁴ Les Français et l'homéopathie, Ipsos, November 2018

⁵⁵ Estudio sobre conocimiento y uso de homeopatía en España, Revista Medica de Homeopatía, 2012

⁵⁶ Sociodemographic profile of the homeopathy user in Spain, Atención Primaria, 2018

⁵⁷ Doxapharma, 2012

⁵⁸ GfK, Homöopathie und pflanzliche Arzneimittel, Umfrage im Auftrag der Dr. Peithner KG, 2018

⁵⁹CAMbrella, 2012

⁶⁰ Allensbach, 2014

⁶¹ Kantar TNS, 2018

⁶² EMG Acqua, 2018

⁶³ EMG Acqua, 2016

- 34% of Belgians use homeopathy on the recommendation of a close friend or relative, while 27% and 25% do so on the recommendation of their doctor or pharmacist respectively, 64 although 36% of Belgians also turn to the internet for information;65
- 70% of users in **Spain** have learnt about homeopathy from friends and acquaintances, 28% from the internet and 23% from a health professional;66
- 44% of French people consider themselves to be quite or very badly informed about homeopathy;67
- In Lithuania, 86% of pharmacists have a positive opinion of homeopathic medicinal products; 47% recommend them often and 49% sometimes. 68 66% of conventional physicians regularly prescribe or recommend a homeopathic product instead of a conventional variant;
- Data from Latvia⁶⁹ show that 82% of pharmacists have a positive attitude towards homeopathic medicinal products; 43% say they recommend them.

1.4.2 Demand for information – the members' experience

ECHAMP members report an ongoing strong and in many cases increasing demand from users, prescribers and pharmacists for reliable information on homeopathic and anthroposophic medicinal products, within the context of a need for information on complementary and alternative medicine.

Most companies have regular contact with consumers, pharmacists and prescribers and generally note either stable communication or an increase in communication over the past three years. Of those who responded, about half reported an increase in interaction with their stakeholders and half a stable level of interaction.

However, at the same time, ECHAMP members report an increasingly restrictive legal environment, limiting their opportunities for publicity or advertising and therefore direct communication with consumers is at best stable and in many cases reduced. In some countries, the difficulties are balanced by an increase in digital interaction and with a reported increase in visits to websites and rising use of social media.

In this context, there is a real business opportunity for pharmacists to step in and offer their customers specialist support to fill the information gap (see 2.4).

⁶⁴ Boiron, 2013

⁶⁵ Ipsos Boiron, 2011

⁶⁶ Sociodemographic profile of the homeopathy user in Spain, Atención Primaria, 2018

⁶⁷ Boiron Ipsos, 2012

⁶⁸ Pharmacy survey (269 pharmacies in 8 cities), Mitela, 2018

⁶⁹ Pharmacy survey (100 pharmacies in 2 cities), Mitela, 2018

Chapter 2

The industry profile – complex and safe

Europe is the global centre of expertise for homeopathic and anthroposophic medicinal products (HAMPs). The sector is characterised by a wide variety of source materials, multiple distinct finished products with different potencies and dosage forms, and big, medium, small and very small batch sizes, requiring sophisticated management to meet the complex quality requirements. Companies balance a significant proportion of non- or lowprofit products within their business models. This section profiles the industry in detail. The data are drawn from the results of two surveys of ECHAMP members (2015 and 2018) and from other referenced sources.

2.1 Economic profile

2.1.1 Employment

The sector employs more than 10,000 people in the EU. Jobs in this sector are mainly in the bigger markets such as Germany, France, Italy or Spain, where the larger companies are located.

2.1.2 Company size

The four largest companies in the sector represent approximately 70% of the total sector turnover; the remaining share of the sector is characterised by a large number of small and medium-sized companies (SMEs).

ECHAMP is the only organisation representing this sector at an international or European level, with 41 member companies of all sizes. According to the European Commission's definition,⁷⁰ ECHAMP's members can be categorised as follows:

- 13% are micro size with less than 10 employees
- 50% are small size with between 10 and 50 employees
- 28% are medium size with between 50 and 250 employees
- 9% are large size with more than 250 employees.

⁷⁰ Internal Market, Industry, Entrepreneurship and SMEs, European Commission: http://ec.europa.eu/growth/smes/business- friendly-environment/sme-definition_en

2.1.3 Hybrid entrepreneurs: combining profitable and non-profitable business

A particular characteristic of HAMPs companies is the wide range of products with low-or no profit margin.⁷¹ Prescribers have expressed a need for 3,000 distinct stocks for the proper practice of these therapies⁷² and many ECHAMP members seek to make this full range available. As a result, the majority of ECHAMP's members produce a significant proportion of products which are not profitable. On average, ECHAMP member companies have:

- 22% high profit margin products;
- 31% medium profit margin products;
- 47% low profit or non-profit products.

It is the case for about one third of ECHAMP's manufacturers that over 50% of the products in their portfolio generate only low or no profit. These figures reflect the considerable effort by HAMPs manufacturers to retain the wide range of products required by their customers, despite the financial pressures on the industry.

The vast majority of ECHAMP member companies (more than 85%) report a negative impact of regulation on their business in the past five years. Many report reduction in the number of products in their portfolios due to the cost of regulatory requirements and the difficulties in achieving them. This means that the less popular finished products are no longer financially viable and companies have had to remove them from the market. In the case of one company, up to 40% of products have been removed from the market due to the increasing regulatory requirements which are not sustainable for small batches. This has resulted in a reduction of about 5% in the value of the portfolio.

2.1.4 Regional distribution

ECHAMP's members are drawn from 16 EU Member States plus Norway and one Extraordinary member from Switzerland. The regional distribution of companies also reflects the general pattern in the EU for the concentration of innovation and industry, as many of the larger HAMPs businesses are located in one of the 'Four Motors for Europe', 73 the highly industrialised regions of Rhône-Alpes in France, Lombardy in Italy, Catalonia in Spain and Baden-Württemberg in Germany. In Baden-Württemberg, 7.5% of the total pharmaceutical turnover of the region is made up of HAMPs companies. 74

⁷¹ Low profit or non-profit margin products mean their profits are equal or less than zero.

⁷² European Committee for Homeopathy: Contribution to discussion at EMA workshop on 27 October 2006, www.ema.europa.eu/docs/en_GB/document_library/Presentation/2009/11/WC500012296.pdf

⁷³ http://www.4motors.eu/en/

⁷⁴ Bedeutung der Komplementärmedizin mit Fokus auf Homöopathie und Anthroposophische Medizin in Baden-Württemberg, Kern, 2015

2.2 Production – starting materials

The ECHAMP member companies all operate according to pharmacopoeia standards and standards for Good Manufacturing Practice (GMP).

Europe is the global centre of pharmaceutical expertise in these products. The pharmaceutical manufacturing processes, including quality monographs for both starting materials and manufacturing methods, are developed in the industry, further developed with expert academic input and confirmed by regulation. They are standardised in the European Pharmacopoeia (Ph. Eur.) and specific national pharmacopoeias, such as Pharmacopée Française (Ph. Fr.), the German Homeopathic Pharmacopoeia (HAB), the Swiss Pharmacopoeia (Ph.Helv.) and the Anthroposophic Pharmaceutical Codex (APC). The sector works to achieve feasible and coherent standards with the different quality traditions of homeopathic and anthroposophic medicinal products in Europe.

2.2.1 Diverse starting materials

HAMPs manufacturers use a wide diversity of natural starting materials. The materials are mainly fresh and dried plants, minerals, chemical substances (salts and metals) or animal materials. Some of those raw materials are fairly uncommon and are used only irregularly and in small quantities.

Most of the manufacturers of homeopathic medicinal products offer a wide range of medicinal products for which the ingredients are derived from more than 1,000 different raw materials. The larger manufacturers may have as many as 1,500-2,000 starting materials. The companies with the widest range of products process over 4,000 different starting materials, so as to ensure the full range of products required for the proper practice of the therapies. Many of the small or medium-sized companies have around 700-800 different starting materials and even the smaller companies or those with a limited range have between 100-200 different starting materials. Very few ECHAMP members have fewer than 100 different starting materials.

To confirm the complexity of this sector, these numbers can be compared to a total of 3,000 active pharmaceutical ingredients (APIs) authorised on the EU market as a whole.⁷⁵

For the majority of ECHAMP members, more than 50% of starting materials are of botanical origin; for some companies, this number can be as high as 80-90%.

We have not been able to quantify the impact of regulation on the numbers of starting materials. It is likely there have been some losses over recent years but this is not quantified.

2.2.2 Sourcing the starting materials

In many cases, this wide variety of starting materials is sourced from multiple suppliers to ensure stability of production, bringing with it additional complexity in quality management. The larger companies can have over 100 different suppliers, with one ECHAMP member company sourcing

⁷⁵ Study on the risks of environmental effects of medicinal products, European Commission, 2013

24 The industry profile – complex and safe

materials from nearly 350 different suppliers. Even the smaller companies or those with limited ranges can have 20 or more different suppliers. In view of the high number of starting materials, flexibility of the choice of suppliers is essential to guarantee availability.

There is a requirement for companies to maintain quality documentation for each different starting material. The quality of each raw material is ensured by internal quality control and by qualifying the supplier according to standard procedures.

2.2.3 Guarantee of quality - medicinal gardens

In order to guarantee the quality and availability of botanical starting materials, one third of surveyed manufacturers have developed their own medicinal gardens - these tend to be the larger companies in Germany or France, who are experts in ecology and biodiversity, growing many of the plants needed for their own products.

The size of garden depends on the company but the number of plants cultivated can be as many as 600 different plant species, including trees. Medicinal plant cultivation is always organic and the land has often been uncontaminated for many years, free from pesticides, chemicals or heavy metals, in some cases for up to 60 years or longer. Water may be from natural sources, also free of chemical residues. Gardens may be cultivated but wild flower areas are also left to grow, resulting in gardens rich in different species and biodiversity for plants and animals, including insects and bees.

The major producers of anthroposophic medicine also place much importance on biodynamic agriculture (see 2.6 The environment – the limited impact of HAMPs).

The companies who invest in this way do so to ensure the quality of raw material for their products; some of those which source plants externally also invest in ensuring the quality of their supply chain, co-operating with certified producers for their raw materials including new plant species as needed.

About 30% of companies who do not yet have a medicinal garden express an interest in having one in the future.

2.3 Production – a diverse portfolio

2.3.1 Finished products

The HAMPs sector offers a very high number of distinct finished products – the ECHAMP member companies market approximately 1.5 million distinct finished products; companies with the widest ranges may have 350,000 distinct finished products in their portfolio or more. This extreme variety of finished products is due to the wide range of starting materials, potencies and dosage forms needed to serve the therapeutic needs of the sector.

From ECHAMP's survey and market analysis, it can be extrapolated that about 200 million units of finished products are produced for EU markets each year. Feedback from ECHAMP members show

that nearly three quarters of all units sold are for oral or sublingual use (e.g. tablets, pillules, drops or capsules); about 12% are for cutaneous use (e.g. creams, ointments); injectables represent less than 3% of units sold; the final 11% include all other forms, for example, nasal, suppositories, eye drops etc.

It varies from company to company and from market to market as to which are the most popular over-the-counter dosage forms. While according to respondents, granules are popular in France, tablets and pillules are more popular in Germany; eye drops have a certain popularity in Germany and Switzerland.

2.3.2 Small batch sizes

The multitude of finished medicinal products of smallest batch sizes differentiates the sector from the rest of the pharmaceutical industry. It is common for producers to release over 30 batches a day, with the larger manufacturers releasing nearly 300 batches a day. Even a small or medium-sized company may typically release up to 70 batches a day. A typical batch size for non-profitable products is between 50 and 100 units.

2.3.3 Products on demand

25% of ECHAMP's members supply products on demand for individual patients in individual batches. ECHAMP's analysis shows that at least 7% of all finished products are produced on demand for individual patients.

Magistral products are prepared in accordance with a prescription for an individual patient, while officinal formulae are kept in stock. About 40% of ECHAMP members sell magistral or officinal formulae of homeopathic and anthroposophic medicinal products.

2.3.4 Prescription-only products

About 2% of the value of the HAMPs market comes from products which are classed as prescription medicines.76

2.4 Commercial distribution

2.4.1 A significant opportunity for pharmacies

98% of the turnover of HAMPs comes from products with a regulatory status of non-prescription medicines.⁷⁷ Pharmacies remain the main channel for the sale of HAMPs – IMS data show that globally, ex-factory prices typically account for about 45% of total in-market sales figures in the pharmaceutical sector; this ratio is confirmed in the sector for HAMPs in the EU by experts in three major markets.78

⁷⁶ ECHAMP calculation based on member information

⁷⁷ ECHAMP calculation based on member information

⁷⁸ Homeopathic and Anthroposophic Medicinal Products in the EU, Profile of an Industry, ECHAMP 2015

81% of homeopathic medicinal products are sold with a direct user-pharmacy contact in Germany;⁷⁹ 87% of Italians purchase their homeopathic medicines in the pharmacy;⁸⁰ 28% of Italian users do so on the recommendation of a pharmacist⁸¹ and over 26% of Italians⁸² think pharmacists should be able to provide the information they need about these medicinal products. Over 60% of Germans⁸³ think it important or very important to be given free choice of medicines in the pharmacy, including conventional medicine, natural medicine or homeopathy. An Australian study⁸⁴ confirms that consumer expectations on the pharmacist as regards complementary medicines included: select the right product for the right person, expert product knowledge and maintaining a wide range of good quality stock.

In this context, there is a real business opportunity for pharmacists to step in and offer their customers specialist support to fill the information gap; educated pharmacists are better able to support their customers' choices.

Three arguments confirm the opportunity for pharmacies to engage in HAMPs:

- this market thrives in the context of a trend towards self-medication and demand for medicines with a high safety profile;
- it offers a field of specialist expertise allowing individual pharmacies to create their own distinct profile;
- HAMPs foster customer loyalty through high level customer contact and individual advice.

The general trend towards over-the-counter medicines also applies to HAMPs. Pharmacies have a clear role to play.

2.4.2 The role of the pharmacist – ECHAMP members' experience

Company investment in the pharmacy sector focuses on providing information and training, with significant results. 60% of ECHAMP members recognise a direct return on their investment in building a relationship with pharmacies. According to these companies, an effective relationship with pharmacies creates confidence in the effectiveness and safety of HAMPs. There are companies who invest up to 30% of their marketing budget in pharmacy training, achieving 20% sales growth.

ECHAMP members report stable or in many cases increased demand for information about their products from pharmacies over the past three years and increased interaction with pharmacists over that period. There is also a perceived increase in demand for training from pharmacists. As the

⁷⁹ ECHAMP calculation – data from Der Arzneimittelmarkt in Deutschland, Zahlen und Fakten, Bundesverband der Arzneimittel Hersteller (BAH) e.V., 2017

⁸⁰ Doxapharma, 2012

⁸¹ EMG Acqua, 2018

⁸² Doxapharma, 2012

⁸³ Kantar TNS, 2018

⁸⁴ Iyer et al, Expectations and responsibilities regarding the sale of complementary medicines in pharmacies: perspectives of consumers and pharmacy support staff, International Journal of Pharmacy Practice, 2016

general environment for advertising about these products is very restricted, companies are aware of the need to provide the right support for pharmacists so that they can provide quality information to the end users.

Many companies, the larger ones in particular, have dedicated sales teams visiting pharmacies in their markets. They prioritise these relationships through additional investment in and enlargement of their sales teams for direct personal visits. One company has seen a growth of 12% of active pharmacies since 2015. It has invested in its relationships with pharmacists by increasing the number of visits by 8% since 2015, managing the relationships mostly through these visits and the supply of educational material, supported also by telephone, webinars and events.

Most of these companies report dedicated education campaigns for pharmacists on specific over-thecounter (OTC) fields of application relating to the homeopathic medicines in their portfolio with indications. Examples include back pain, urinary tract infection, integrative support for chronic disease such as rheumatic complaints, transition periods in early childhood, flu, colds and respiratory tract infections, allergies, gastrointestinal disorders, headache, insomnia, stress and restlessness, sports injuries and pain.

In addition, all companies who report sales either direct to pharmacies or indirectly via wholesalers offer dedicated training programmes for pharmacists. In most cases, this is offered by the sales force to help with recommending the medicines, supported by telephone back up for specific queries. In addition, many companies offer additional training events. These might be in-person seminars, lectures, symposia or practical training at external venues or in-house training for a company and its employees; in rare cases companies also offer webinars. One company runs its training through the professional association allowing pharmacists to benefit from accredited professional development. Some members point out the importance of providing education and training not just for pharmacy owners but for the pharmacy assistants as well. One company sponsors a prize for young pharmacists in its sector.

2.4.3 E-commerce sales

According to global trends, 85 e-commerce has increasing importance in the OTC market place. While it currently represents a small share of global OTC sales, it is growing very quickly. This is driven in part by changing consumer behaviour as consumers become better informed, engage online, try to better understand and manage their own health and to embrace healthy lifestyles. Different generations of consumers mean different behaviours.

Mail order sales volumes of all pharmaceuticals in Germany represent 14.3% of all sales in 2016, compared to only 11.7% in 2013. Mail order sales of homeopathic medicinal products are slightly

^{85 54}th AESGP Annual Meeting conference report – Connecting the smart consumer

higher than the industry average, with between 17% and 19% of all homeopathic medicinal products in Germany in 2017 sold by mail order. 86 This trend remains to be monitored.

Other than in Germany, there is no precise data on the share of e-commerce in EU market but company feedback is that internet sales represent an increasingly significant share of product sales. Estimates confirm the German experience above, suggesting that the value is between 10-15% of the total market with double digit growth in some markets.

Specifically, feedback from ECHAMP members indicate that the growth in the last few years of internet sales is due to growth in sales volume of homeopathic and anthroposophic medicinal products by large internet pharmacies. One company suggests that as many as 40% of German pharmacies sell over-the-counter homeopathic remedies on line. Relatively few companies report internet sales of their own, listing their products with internet pharmacies and not wishing to undermine the pharmacies who are their main customers by offering products direct to end consumers. They are also restricted by laws concerning distribution of medicinal products. In this framework, some report increase in e-sales; one company reports this has become a significant element of the sales turnover, with constant growth over the last eight years.

2.5 Safety profile

A variety of different methods of analysis make visible the overall safety profile of homeopathic and anthroposophic medicinal products (see also 3.2).

Firstly peer reviewed articles confirm a high safety profile of these products: Hamre et al⁸⁷ found 70.1 adverse drug reactions (ADRs) for each 100,000 prescriptions of anthroposophic medicinal products (these mostly comply with the legal definition of homeopathic medicinal products). For injectable homeopathic and anthroposophic medicinal products, Baars et al⁸⁸ found one adverse drug reaction per 250,000 ampoules sold, classified as very rare.

Data from ECHAMP member companies confirm these overall safety findings. In 2016, the number of adverse drug reactions reported to ECHAMP member companies was less than 1 in each 200,000 units sold.⁸⁹

⁸⁶ ECHAMP calculation – data from Der Arzneimittelmarkt in Deutschland, Zahlen und Fakten, Bundesverband der Arzneimittel Hersteller (BAH) e.V., 2017 and BPI PharmaDaten 2017

⁸⁷ Hamre, Glockman, Heckenbach, Matthes, Use and Safety of Anthroposophic Medicinal Products: An Analysis of 44,662 Patients from the EvaMed Pharmacovigilance Network, Published Drugs - Real World Outcomes (2017) 4:199–213

⁸⁸ Jong, Jong, Baars, Adverse drug reactions to anthroposophic and homeopathic solutions for injection: a systematic evaluation of German pharmacovigilance databases, Pharmacoepidemiology and drug safety (2012), DOI: 0.1002/pds.3298

⁸⁹ The data presented from answers collected from ECHAMP members are not directly comparable with the data of the quoted scientific articles. ECHAMP data is based on ADRs collected and managed by its member companies in relation to the units sold. The Baars et al study refers to ampoules sold. The Hamre et al study refers to prescriptions of anthroposophic medicinal products.

Of the low number of ADRs reported by ECHAMP members in the survey, over half (51%) were for oral or sublingual methods of dosage, 11% for cutaneous doses, 6% for injectables and 31% for other forms of dosage (nasal, auricular, vaginal, rectal or opthalmic). Relative to the breakdown of unit sales in those categories, the lowest incidence of ADRs relates to oral and sub-lingual use and the highest to products in the 'other' category of route of administration.

The comparatively higher ratio found with products in the 'other routes of administration' category can be explained by noting that these particular medicinal products are often applied locally at the site of the complaint, in contrast to the normal use of oral/sublingual dosage forms. Local application may be to a particularly sensitive site, such as a mucous membrane. In these conditions, excipients or the more concentrated active ingredients may trigger reactions. In addition, with local applications, if the local complaint does not improve as expected by the patient, the patient may assume that the disease itself is an ADR.

2.6 The environment – the limited impact of HAMPs

The European Commission describes environmental pollution caused by human and veterinary pharmaceutical substances as 'an emerging environmental problem'90 and its 'Study on the environmental risks of medicinal products'91 confirms that some medicinal products pose environmental risks and that there are concerns for the health effects on humans. Health and environmental regulators, academics and the pharmaceutical industry are working to assess the situation and find solutions.

HAMPs have negligible environmental impact, making this 'one of the most eco-friendly and sustainable forms of healthcare on the planet'. 92 There is negligible toxicity from the active substances of these products, the majority of which are of botanical origin.

In addition, the sector for HAMPs fosters environmental protection and biodiversity. Most ECHAMP members take measures to promote organic farming, biodynamic agriculture and biodiversity. They foster biodiversity through organic cultivation of plants. Much of the sector is committed to organic farming for its source materials, whether in their own medicinal gardens (one third of surveyed manufacturers) or by working with appropriately certified suppliers. Anthroposophic medicine manufacturers are pioneers in cultivating their gardens in accordance with Demeter biodynamic agriculture practices, 93 complying with EU standards for organic farming. The practice of biodynamic agriculture preserves nature, increases soil fertility, and enhances biodiversity.94

⁹⁰ https://ec.europa.eu/health/human-use/environment-medicines_en

⁹¹ https://ec.europa.eu/health/sites/health/files/files/environment/study_environment.pdf

⁹² K. Chatfield, Simile, Faculty of Homeopathy, November 2016

⁹³ https://www.demeter.net/what-is-demeter

⁹⁴ Organic farming enhances soil fertility and biodiversity, FIBL, 2000

Many ECHAMP members take additional measures to ensure minimal negative environmental impact from their suppliers and manufacturing processes. Other quality standards have been introduced in this sector, such as Ecocert – certification for sustainable development, ⁹⁵ Demeter – certification for biodynamic agriculture, ⁹⁶ EU-Organic ⁹⁷ and Soil Association. Some ECHAMP members hold certificates relating to high environmental standards, such as ECOfit: certification by the state of Baden-Württemberg for corporate environmental protection, ⁹⁸ Member of Organic Trust, ⁹⁹ ISO 14001, certification for environmental management and EMAS, Eco-Management and Audit Scheme. ¹⁰⁰

Furthermore, companies have effective policies and methods to optimise their use of natural resources, for example:

- increasing the use of rainwater while cutting the use of water from public supply;
- reducing direct and indirect energy consumption, increasing the use of renewable energy, cutting down greenhouse gas emissions, increasing the use of biogas;
- using packaging manufactured from sustainable raw materials that is recyclable while at the same time achieving a high level of safety and being consumer-friendly;
- reducing waste intensity (waste volume per tonne of manufactured products) and increasing the use of recycled materials.

ECHAMP manufacturers pay attention to promoting fair trade with suppliers. One large group has implemented the external Union for Ethical Biotrade (UEBT), ¹⁰¹ which ensures manufacturers' procurement to support biodiversity, respect traditional knowledge and guarantee fair remuneration of all partners throughout the supply chain.

2.7 Increasing co-operation with academia

HAMPs have an established tradition and long-standing use; at the same time, the key actors in this sector contribute to the debates and requirements of modern science. These medicinal products are increasingly the subject of basic as well as clinical research.¹⁰² A trend towards increasing cooperation with the academic sector can be perceived amongst ECHAMP members.

⁹⁵ http://www.ecocert.com/en/

⁹⁶ https://www.demeter.net

⁹⁷ http://ec.europa.eu/agriculture/organic/downloads/logo/index_en.htm

⁹⁸ https://um.baden-wuerttemberg.de/de/wirtschaft/betrieblicher-umweltschutz/foerdermoeglichkeiten/foerderprogrammecofit/

⁹⁹ http://organictrust.ie/

¹⁰⁰ http://ec.europa.eu/environment/emas/index_en.htm

¹⁰¹ http://ethicalbiotrade.org/

¹⁰² Homeopathy Research Institute, https://www.hri-research.org/

70% of responding ECHAMP members, and in particular the larger companies, invest in projects with scientific or academic institutions. On average, between 2-3% of employees work in scientific departments; between 2013 and 2016, this number went up by over 13%.

Projects may relate directly to manufacturing issues, such as pharmacopoeial work, specific manufacturing methods, plant cultivation and research, toxicology, validation issues and safety questions. Companies also provide substantial financial support for academics and scientists working in basic and pre-clinical research, specifically for those who are exploring the mechanism of action of homeopathy.

A limited number of companies support or develop clinical research and there are company reports of specific collaboration with universities, supporting and publishing clinical research. Some companies also make a donation to university funds, allowing research to go ahead, including metaanalyses or literature reviews.

Another initiative is to help build important networks of academics and non-academic research institutes for scientific exchange, with the aim of stimulating scientific research and discussion, also of political issues for which reliable data can contribute to problem solving globally, for example antimicrobial resistance. The results of such collaboration are communicated in scientific symposia, congresses and peer-reviewed publications at national and international level.

In addition, many companies help with education in the sector, providing sponsorship to academic, scientific or medical events or courses, for example: medical lectures, congress or symposia sponsorship; sponsorship of academic courses - both sector specific and more general for complementary medicine; the sponsorship of a research award; sponsorship of internships for students; post-graduate University-certificated development courses for doctors and pharmacists.

Chapter 3

Added value of the sector

Homeopathy and anthroposophic medicine and their related products have an important contribution to make towards major health challenges in the EU. Research in these fields confirms significant added value to society. These include clinical effectiveness, low incidence of side effects and costeffectiveness. In addition, these therapies and their medicinal products have a role to play in fields of specific relevance to EU health policy, such as antimicrobial resistance, polypharmacy, chronic diseases and healthy ageing.

3.1 Clinical effectiveness

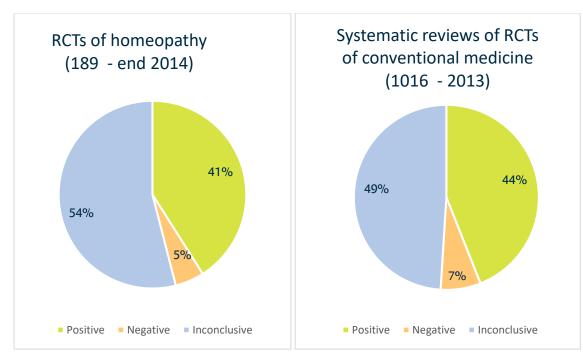
To date, 1218 clinical trials of homeopathy have been published in the research literature. Of these, 371 are randomized placebo-controlled trials (RCTs).¹⁰³ A sub-group analysis of the RCTs published up to the end of 2014 found 189 peer-reviewed papers with usable data, 104 of which were placebocontrolled. When looking at the results of these studies, 41% reported positive findings, 5% were negative and 54% were non-conclusive. 104

When compared to conventional medicine the percentages of positive, negative and inconclusive findings per treatment are remarkably similar (see Figure 3). 105 However, the data available for conventional medicine is at the level of the systematic review whereas for homeopathy, it is at the level of the RCT.

¹⁰³ https://www.carstens-stiftung.de/databases/#/corehom [Accessed July 2018]

¹⁰⁴ http://facultyofhomeopathy.org/randomised-controlled-trials/

¹⁰⁵ www.hri-research.org/resources/homeopathy-the-debate/there-is-no-scientific-evidence-homeopathy-works/



Source: Homeopathy Research Institute/Faculty of Homeopathy

Figure 3: How do randomised controlled trials of homeopathy compare with evidence for conventional medicine?

In addition, there have been seven peer-reviewed systematic review papers published on homeopathy as a whole including all conditions: five have been broadly positive, 106 one tentatively positive 107 and one negative.108

A number of government reports have also been produced contributing to the non-peer reviewed 'grey literature' which is frequently used to make decisions about provision and regulation of homeopathy and other CAM therapies. One such 'grey' report of note is the 2015 Australian National Health and Medical Research Council (NHMRC) report, 109 which is highly negative towards homeopathy and fails on scientific rigour, demonstrating significant bias and lack of balance. The NHMRC report is currently being challenged through the Commonwealth Ombudsman on the grounds of scientific and procedural misconduct.¹¹⁰ A similarly negative and biased report is the 2017 European Academies' Scientific Advisory Council (EASAC) statement on homeopathy. 111

Most importantly, a recent high quality, scientifically robust systematic review of individualised homeopathic treatment – i.e. usual care as practised by homeopathic practitioners – shows that

¹⁰⁶ Kleijnen et al., BMJ, 1991, 302:960; Linde et al., Lancet, 1997, 350:834; Linde et al., J.Clin.Epidemiol., 1999, 52:631; Cucherat et al., Eur.J.Clin.Pharmacol., 2000, 56:27; Mathie et al., Sys.Reviews, 2014, 3:142

¹⁰⁷ Mathie et al., Sys.Reviews, 2017, 6:63

¹⁰⁸ Shang et al., Lancet, 2005, 366:726

¹⁰⁹ https://www.hri-research.org/wp-content/uploads/2015/07/NHMRC-Information-Paper-Mar2015.pdf

¹¹⁰ https://www.hri-research.org/resources/homeopathy-the-debate/the-australian-report-on-homeopathy/

¹¹¹ https://easac.eu/publications/details/homeopathic-products-and-practices/

homeopathy is 1.5- to 2-times more likely to have a beneficial effect than placebo. 112 This study was not included in either of the negative NHMRC or EASAC documents.

There is also an emerging evidence base indicating that homeopathy may be effective for specific medical conditions. For example, high quality studies have shown homeopathy to perform better than placebo for conditions such as seasonal allergic rhinitis, sinusitis, childhood diarrhoea, vertigo113 and depression.114

The most recent comprehensive systematic review of clinical studies of anthroposophic medicine treatment included a total of 265 studies. 115 The authors concluded that anthroposophic medicine therapy for a broad spectrum of disorders showed predominantly good results with few side effects, a high measure of client satisfaction and a favourable cost-effectiveness profile, compared to conventional treatment.

Studies comparing the effectiveness of homeopathy or anthroposophic medicine and conventional medicine have shown that homeopathy can produce results as good as or better than conventional medicine for some conditions and treatment options. 116, 117 However, a full and systematic assessment of comparative effectiveness for homeopathy and anthroposophic medicine is currently lacking in the research literature.

Looking at the clinical evidence beyond the artificial structure of an RCT, there is a growing body of published observational studies in support of the real-world effectiveness of homeopathy across Europe. 118 For example, in Germany, disease severity and quality of life demonstrated marked and sustained improvements following homeopathic treatment in patients who had been chronically sick for a long time before study entry and in most cases treated conventionally before. The results persisted for as long as eight years (see Figure 4).119

¹¹² Mathie et al., Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and metaanalysis, Systematic Reviews 2014, 3:142

¹¹³ https://www.hri-research.org/resources/essentialevidence/evidence-by-condition/

¹¹⁴ Viksveen P, et al. Homeopathy in the treatment of depression: a systematic review. Eur J Integr Med 2018; Sept: 22-36

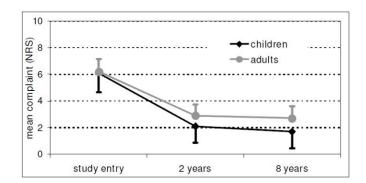
¹¹⁵ Kienle et al., 2006 https://www.ncbi.nlm.nih.gov/pubmed/16883076; Kienle et al., 2011 https://www.ncbi.nlm.nih.gov/pubmed/22105040

¹¹⁶ www.hri-research.org/resources/essentialevidence/conventional-medicine/

¹¹⁷ Hamre et al, Anthroposophic vs. conventional therapy of acute respiratory and ear infections: a prospective outcomes study, 2005 https://www.ncbi.nlm.nih.gov/pubmed/15926617

¹¹⁸ https://www.hri-research.org/resources/essentialevidence/observational-studies/

¹¹⁹ Witt et al: How healthy are chronically ill patients after eight years of homeopathic treatment? Results from a long term observational study. BMC Public Health 2008; 8:413



Numeric rating scale with 10 = maximum severity, 0 = no complaints.

Source: Witt et al., 2008

Figure 4: Improvement over time of patients with a chronic disease with an average duration of 8 years, treated with homeopathic medicine

Similarly, in the Tuscany region of Italy, after 20 years of clinical experience of providing homeopathy integrated into the public healthcare system, data collected from 5,877 patients shows that 88.8% of patients experienced health improvements, with a significant improvement seen in 68.1%.120

Finally, in France, a major study – called the EPI-3 study – followed 8,559 patients attending GP practices for a year and looked specifically at the 'real-world' effectiveness of treatment provided by certified homeopathic physicians for three main groups of clinical conditions: namely, musculoskeletal disorders, upper respiratory tract infections and sleep/anxiety/depressive disorders. In all three clinical groups the results showed that patients accessing homeopathy experienced symptomatic improvement, coupled with reduction in exposure to drugs with side effects, antibiotics and psychotropic drugs with addictive properties respectively. 121

3.2 Low incidence of side effects

Safety is a major issue for the pharmaceutical sector, with the EU giving priority to laws and processes on pharmacovigilance. In 2017, 543,548 reports related to suspected adverse drug reactions were collected and managed in EudraVigilance within the European Economic Area (EEA).122

In this context, HAMPs have an important role to play, as they can generally be regarded as safe (see also 2.5). This is further demonstrated by the following scientific literature:

¹²⁰ Rossi E, et al. Integration of Homeopathy and Complementary Medicine in the Tuscan Public Health System and the Experience of the Homeopathic Clinic of the Lucca Hospital. Homeopathy 2018; 107(2):90-98

¹²¹ https://www.hri-research.org/resources/essentialevidence/observational-studies/

^{122 2017} Annual Report on EudraVigilance for the European Parliament, the Council and the Commission (EMA): www.ema.europa.eu/docs/en_GB/document_library/Report/2018/03/WC500245914.pdf

- a systematic review of the safety of homeopathy¹²³ concluded adverse effects provoked by homeopathic medicines are generally mild and transient; in two studies included in the systematic review, only 2.7% of the patients^{124, 125} reported adverse reactions; in the third study, 7.8% of homeopathy patients (mainly paediatric cases with specific acute pathology) had adverse reactions, compared to 22.3% in the corresponding group receiving conventional treatment;
- other studies confirm the safety, showing that when applied properly, classical homeopathy has few side-effects and the use of high-potencies is free from toxic effects; 126, 127
- a thorough systematic evaluation of collected and spontaneous reported side effects for injectables of anthroposophic and homeopathic medications indicates that injectables as applied in anthroposophic medicine and homeopathy have an excellent safety profile.¹²⁸

3.3 Cost-effectiveness

A number of scientific research studies evaluate the cost-effectiveness of homeopathic and anthroposophic medicines. It is plausible to state that both homeopathic and anthroposophic medicines can contribute to sustainable health systems by significantly reducing treatment costs.¹²⁹

The following are examples of specific health care situations with clear data on cost-effectiveness:

- in Germany, 493 patients treated by GPs for chronic conditions with homeopathy had better clinical outcomes than those treated with conventional medicine, for similar costs;¹³⁰
- a study comparing the costs generated by conventional, homeopathic and mixed medical practice in French general medicine found homeopathic GPs to be up to 20% less expensive than conventional medicine GPs; homeopathic GPs prescribed noticeably fewer psychotropic drugs, antibiotics and non-steroidal anti-inflammatory drugs;131

¹²³ Dantas F, Rampes H (2000). Do homeopathic medicines provoke adverse effects? A systematic review. British Homeopathic Journal, 89 (Suppl 1):S35-S38

¹²⁴ Anelli M, Scheepers L, Sermeus G, Van Wassenhoven M (2002). Homeopathy and health related Quality of Life: a survey in six European countries. Homeopathy, 91:18-21

¹²⁵ Endrizzi C, Rossi E, Crudeli L, Garibaldi D (2005). Harm in homeopathy: aggravations, adverse drug events or medication errors? Homeopathy, 94:233-240

¹²⁶ Stub et al., Risk in homeopathy - Classification of adverse events and homeopathic aggravations, Complementary Therapies in Medicine, 2015

¹²⁷ Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs. Gudrun Bornhöft & Peter F. Matthiessen (Editors), 2011

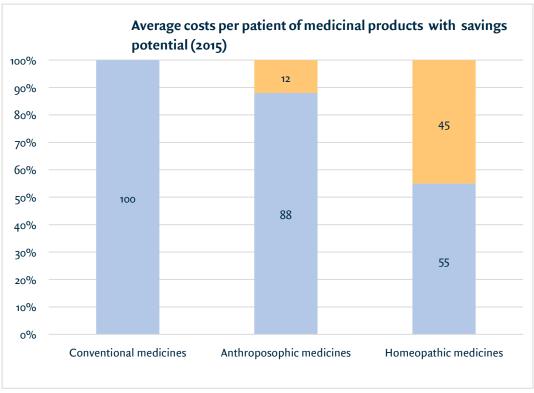
¹²⁸ Jong, Baars et al., Adverse drug reactions to anthroposophic and homeopathic solutions for injection: a systematic evaluation of German pharmacovigilance databases, Pharmacoepidemiology and Drug Safety Volume 21, Issue 12, pages 1295–1301, December 2012

¹²⁹ Reducing healthcare costs with homeopathy and anthroposophic medicine: A summary of available literature, ECHAMP

¹³⁰ Witt et al: Outcome and costs of homoeopathic and conventional treatment strategies: a comparative cohort study in patients with chronic disorders. Complement Ther Med. 2005 Jun;13(2):79-86

¹³¹ Colas et al., Economic impact of homeopathic practice in general medicine in France, Health Econ Review, 2015; 5: 18, 8 Jul 2015

- an Italian study¹³² shows savings of more than 40% for patients with respiratory diseases under homeopathic treatment versus conventional therapy; after the first year, the spending decreased by 42% with a further reduction of 13% in the second year, representing a cost saving of 50% in total over the two years;
- another study on recurrent upper respiratory tract infection showed homeopathic treatment to have superior medical effectiveness, fewer complications, fewer consultations, better quality of life, and less parental time off work – for equivalent direct medical costs;¹³³
- Swiss insurance company data show that homeopathic and anthroposophic medicinal products offer potential savings of 45% and 12% respectively compared to conventional medicines¹³⁴ (see Figure 5).



Source: SASIS-Datenpool Jahresdaten mit Abzugsdatum 2015, SVKH

Figure 5: Cost savings of homeopathic and anthroposophic medicinal products in relation to conventional medicines

3.4 Relevance to EU health policy

With the growing focus on tackling global health challenges, increasing value can be given to the potential role of homeopathy and anthroposophic medicine to support national government and European and worldwide initiatives. The following outline the contribution of these medicines in

¹³² Rossi et al., Cost-benefit evaluation of homeopathic v conventional therapy in respiratory diseases Homp (2009) 98:2-10

¹³³ Trichard M et al., Pharmacoeconomic comparison between homeopathic and antibiotic treatment strategies in recurrent acute rhinopharyngitis in children. Homeopathy 2005:94:3-9

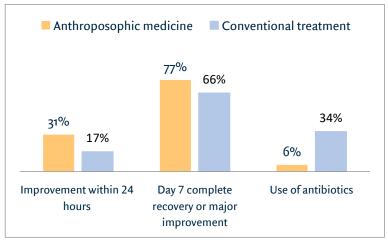
¹³⁴ SASIS-Datenpool Jahresdaten mit Abzugsdatum 2015, SVKH

areas particularly prioritised by EU health policy, in line with the third Health Programme (2014-2020).

3.4.1 Antimicrobial resistance

EU action in public health gives priority to tackling the emerging global threat of antimicrobial resistance and over-prescription of antibiotics in primary care, 135 a growing global problem with important consequences such as increased mortality and economic impact. It is estimated that resistance to antibiotics results in 25,000 deaths per year in the EU and costs the EU EUR 1.5 billion per year in healthcare costs and productivity losses. The use of effective and safe non-antibiotic treatments of infections is one of the strategies to reduce (inappropriate) use of antibiotics.

In this context, homeopathy and anthroposophic medicine have an important role to play - the use of anthroposophic medicine has been associated with much lower use of antibiotics and antipyretics, quicker recovery, fewer adverse reactions, and greater therapy satisfaction compared to conventional medicine (see Figure 6). 136 Similar results have been seen in homeopathy, 137 with one study, for example, showing lower use of antibiotics and fewer antipyretic/anti-inflammatory drugs for a similar clinical evolution. 138



Source: Hamre et al.(2005)

Figure 6: Patients treated for acute respiratory and ear infections, comparing anthroposophic medicine with conventional treatments

3.4.2 Polypharmacy

A key public health challenge for Europe is to address the issue of inappropriate polypharmacy and non-adherence as the population ages. With a growing cultural reliance on pharmaceutical

¹³⁵ https://ec.europa.eu/health/amr/

¹³⁶ IIPCOS study, Hamre H.J. et al., Anthroposophic vs. conventional therapy of acute respiratory and ear infections: a prospective outcomes study. Wien. Klin Wochenschr (2005) 117/7-8: 256-268;

¹³⁷ IIPCOS study, Haidvogl, M et al.: Homeopathic and conventional treatment for acute respiratory and ear complaints: A comparative study on outcome in the primary care setting, BMC Complement Altern Med. 2007; 7: 7.

¹³⁸ Grimaldi-Bensouda et al., Management of upper respiratory tract infections by different medical practices, including homeopathy and consumption of antibiotics in primary care: the EPI3 cohort study in France 2007-2008. PLoS One 2014 19; e89990.doi: 10.1371/journal.pone.0089990

interventions to manage health conditions, the issue of polypharmacy is becoming increasingly pressing, especially coupled with the increasing prevalence of chronic diseases and multimorbidity. It is common for older adults to be prescribed at least five drugs simultaneously, 139 which in turn increases the risk of adverse drug reactions and side effects.

In tackling these issues, studies justify consideration of the ability of homeopathy and anthroposophic medicine to reduce reliance on conventional drugs. For example, as noted in the EPI-3 studies for sleep, anxiety and depressive disorders, patients treated by certified homeopathic physicians were less likely to be prescribed psychotropic drugs, reducing their usage and avoiding their addictive potential.¹⁴⁰ Similarly, patients with musculoskeletal disorders treated with homeopathy did as well clinically as those treated with conventional medicine but used only half the amount of non-steroidal anti-inflammatory drugs (NSAIDs) and had fewer NSAID-related side effects.141

3.4.3 Chronic diseases

Non-communicable diseases, such as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes, are the leading cause of mortality in the EU, representing major causes of disability, illhealth, health-related retirement, and premature death, resulting in considerable social and economic costs. Every year in the EU, approximately 550,000 people of working age die prematurely from non-communicable diseases. They account for most healthcare expenses, costing EU economies €115 billion annually.142

The case load of a homeopathic practitioner tends to be more heavily weighted towards chronic diseases, particularly those where conventional medicine has failed or has limited options. The aforementioned study¹⁴³ demonstrated marked and sustained improvements to disease severity and quality of life following homeopathic treatment in patients who had been chronically sick for a long time before study entry and in most cases treated conventionally before. Given the promising body of evidence for homeopathy in chronic diseases such as Irritable Bowel Syndrome (IBS), 144 fibromyalgia¹⁴⁵ and osteoarthritis, ¹⁴⁶ such complementary therapies offer a therapeutic option which can be implemented in addition to usual care, where there is significant clinical need.

¹³⁹ https://www.ncbi.nlm.nih.gov/pubmed/30015057

¹⁴⁰ Grimaldi-Bensouda, L. et al. Who seeks primary care for sleep, anxiety and depressive disorders from physicians prescribing homeopathic and other complementary medicine? Results from the EPI3 population survey. BMJ Open, 2012; 2 ¹⁴¹ Rossignol, M. et al. Impact of physician preferences for homeopathic or conventional medicines on patients with musculoskeletal disorders: results from the EPI3-MSD cohort. Drug Saf., 2012; 21: 1093-1101

¹⁴² https://ec.europa.eu/health/non_communicable_diseases/overview_en_

¹⁴³ Witt et al: How healthy are chronically ill patients after eight years of homeopathic treatment? Results from a long term observational study. BMC Public Health 2008; 8:413

¹⁴⁴ https://www.ncbi.nlm.nih.gov/pubmed/24931748; http://cochranelibrarywiley.com/doi/10.1002/14651858.CD009710.pub2/full

¹⁴⁵ https://academic.oup.com/rheumatology/article/43/5/577/1788410; https://www.ncbi.nlm.nih.gov/pubmed/19358959

¹⁴⁶ https://www.ncbi.nlm.nih.gov/pubmed/11212088

3.4.4 Healthy ageing

Finally, as the incidence of chronic diseases continues to increase, their impact on an ageing population will also increase, especially in light of growing problems of multimorbidity, polypharmacy and adverse drug reactions – to which elderly people are particularly vulnerable. Although no formal research has yet been done to assess the potential role of homeopathy and anthroposophic medicine in healthy ageing and prevention of age-related disease, the body of evidence described above clearly suggests a role in reducing drug-load, reducing risk of adverse drug reactions and improving the mental health and wellbeing of individuals ≥65 years old.¹⁴⁷

In addition, there is promising evidence for the role of homeopathy in supporting the management of age-related musculoskeletal and rheumatologic disorders such as back pain, rheumatoid arthritis and osteoarthritis, as well as complaints associated with menopause. 148, 149, 150

¹⁴⁷ Danno et al. Management of Anxiety and Depressive Disorders in Patients ≥ 65 Years of Age by Homeopath General Practitioners versus Conventional General Practitioners, with Overview of the EPI3-LASER Study Results. Homeopathy 2018; 107(2):81-89

¹⁴⁸ Morris et al., Physiotherapy and a Homeopathic Complex for Chronic Low-back Pain Due to Osteoarthritis: A Randomized, Controlled Pilot Study. Alt Ther Health Med. 2016 https://www.ncbi.nlm.nih.gov/pubmed/26773321

¹⁴⁹ Long et al., Homeopathic remedies for the treatment of osteoarthritis: a systematic review. Br Homeopath J., 2001. https://www.ncbi.nlm.nih.gov/pubmed/11212088

¹⁵⁰ Edel et al., Individualized homeopathic treatment and fluoxetine for moderate to severe depression in peri- and postmenopausal women (HOMDEP-MENOP study): a randomized, double-dummy, double-blind, placebo-controlled trial. PLoS 2015 https://www.ncbi.nlm.nih.gov/pubmed/25768800

Annex I: Prescribers of HAMPs in the EU (2018)

COUNTRIES	Total no. of homeopathic prescribers 2018	Homeo- pathic prescribers per 100,000 inhabitants 2018	Practising doctors per 100,000	% homeopathic prescribers/practising doctors per 100,000 inhabitants	Number of anthropo- sophic doctors	Number of anthropo- sophic doctors per 100,000 inhabitants
AUSTRIA	470	5. 47	510	1.07%	11-100	0.1-1.2
BELGIUM	561	4.96	300	1.65%	11-100	0.1-0.9
BULGARIA	1,773	24.97	400	6.24%	<10	<0.1
CROATIA	130	3.17	310	1.02%	-	-
CYPRUS	21	2.63	340	0.77%	0	0
CZECH REP	1,924	18.32	370	4.95%	11-100	0.1-1.0
DENMARK	30	0.53	370	0.14%	11-100	0.2-1.8
ESTONIA	25	1.92	330	0.58%	11-100	0.8-7.7
FINLAND	118	2.19	300	0.73%	11-100	0.2-1.9
FRANCE	5,500	8.25	330	2.50%	101-1000	0.2-1.5
GERMANY	8,879	10.79	410	2.63%	>1088	>1.3
GREECE	197	1.82	630	0.29%	0	0
HUNGARY	1,250	12.76	330	3.87%	<10	<0.1
IRELAND	200	4.26	280	1.52%	<10	<0.2
ITALY	8,000	13.20	390	3.38%	101-1000	0.2-1.7
LATVIA	96	5.05	320	1.58%	11-100	0.6-5.3
LITHUANIA	210	7.50	430	1.74%	<10	<0.4
LUXEMBG	10	2.00	290	0.69%	0	0
MALTA	5	1.25	370	0.34%	0	0
NETHERL.	921	5.45	340	1.60%	101-1000	0.6-5.9
POLAND	5,300	13.98	230	6.08%	11-100	0.03-0.3
PORTUGAL	120	1.17	440	0.26%	<10	<0.1
ROMANIA	4,090	20.76	270	7.69%	11-100	0.1-0.5
SLOVAKIA	2,598	48.11	340	14.15%	0	0
SLOVENIA	120	5.71	280	2.04%	0	0
SPAIN	2,808	6.05	380	1.59%	11-100	0.02-0.2
SWEDEN	47	0.47	410	0.11%	11-100	0.1-1.0
UK	2,182	3.34	280	1.19%	11-100	0.02-0.2

^{&#}x27;Homeopathic prescribers' equals the sum of homeopathic doctors plus homeopathic practitioners Source: ECHAMP 2018, ECH 2015, ECCH 2017, IVAA 2016, OECD 2015, Report Health at a glance (European Commission)

About ECHAMP

The aim of ECHAMP, the European Coalition on Homeopathic and Anthroposophic Medicinal Products, is to enable its members to meet the demand from users and prescribers across the EU for these medicinal products.

ECHAMP recognises the important role that homeopathy and anthroposophic medicine play and can play in health care. It works to develop the industry for homeopathic and anthroposophic medicinal products so as to ensure availability of medicines for self-medication and medicines recommended by prescribers.

ECHAMP advocates and supports standards and requirements, including for effectiveness, that are in line with the tradition and therapeutic systems of homeopathy and anthroposophic medicine as practised in Europe. It advocates an appropriate and well-balanced EU regulatory environment that reflects and ensures the specific quality and high safety of homeopathic and anthroposophic medicinal products, and it works to establish the industry as a credible and reliable player in health care so as to maximise political impact at EU level.

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