

Homeopathic and Anthroposophic Medicinal Products in the EU

Profile of an industry 2015



European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

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Introduction

This publication presents unique and up-to-date data on the EU industry for homeopathic and anthroposophic medicinal products. It provides a comprehensive review of the sector and its contribution to both European health care and the EU pharmaceutical sector, and is the only source for summarised EU data on this sector.

Data is drawn from a number of sources: publicly available statistics and data, market studies, published and peer-reviewed research, data from ECHAMP partners and other stakeholders, and a detailed survey of ECHAMP Full Members, the companies who manufacture and distribute these products in the EU. The survey was carried out during the first half of 2015 and responses were received from almost all ECHAMP Full Members. This data has been analysed in detail, and compiled to present specific patterns and trends within the industry and the sector.

Chapter 1 reports on up-to-date sales data for the industry, identifying a number of important EU trends; **Chapter 2** quantifies 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; **Chapter 3** presents, for the first time, a detailed profile of the industry and its manufacturing processes; **Chapter 4** demonstrates the value that homeopathy and anthroposophic medicine and their medicinal products can add to health care in the EU, in terms of effectiveness, safety, cost-effectiveness and patient satisfaction; it refers to quality published and peer-reviewed studies and research; and **Chapter 5** provides a summary of the legal and regulatory situation for these products in the EU and how the companies work within this framework.

The overall message of this analysis is clear: this is an established and growing EU-based industry that serves the needs of millions of European citizens; it offers significant benefit and service to users and prescribers of these products; it has a valuable contribution to make to healthcare systems and Europe-wide health policy challenges.

The industry has a unique profile. It is characterised by its ability to manage a huge and diverse portfolio of safe medicinal products of excellent quality, including both profitable and often low- or no-profit ‘service’ products, meaning a high level of both technical and entrepreneurial complexity.

A healthy regulatory governance of this industry sector must take its specific characteristics into due account.

Christiaan Mol
General Secretary

Executive summary

Growing demand and a growing industry: experts in complexity

New figures value the market for homeopathic and anthroposophic medicinal products (HAMPs) in the EU at €1,237 million (ex-factory prices) in 2013. This represents 7% of the total EU market for non-prescription products, or as high as 15% in one mature market. From 2010 to 2013, the average annual growth was 6.5%, and the number of employees in the sector increased by 25%. SMEs account for 30-40% of sector turnover.

There is significant to high demand for HAMPs in at least two thirds of EU Member States, including those both with and without a long-term tradition for these products. Countries with high sales of HAMPs per inhabitant are France, Germany, Bulgaria, Italy, Lithuania, Latvia, Austria and Belgium; and countries with an above average number of homeopathic prescribers per head include Bulgaria, Czech Republic, Hungary, Italy, Poland, Romania and Slovakia.

The Central and Eastern European markets are growing faster than those in Western Europe, but those more established markets are also home to high and increasing awareness of homeopathy, with these medicines used by up to 60% of the populations. Users tend to be female, aged 30-50, educated and reasonably affluent. Word-of-mouth recommendation is an important driver for new users, and there is a clear opportunity for pharmacists to provide better information to users of these medicinal products.

Europe is the global centre of expertise for the manufacture of these products. The sector produces 100 million units of finished products each year and is characterised by complexity and variety, requiring 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. At least 7% of finished products are produced in individual batches on demand for individual patients.

As a result, the majority of ECHAMP's members produce a significant proportion of products which are not profitable - one third of ECHAMP's members have portfolios in which over 50% of the products generate only low or no profit, requiring innovative business models.

HAMPs have negligible environmental impact. In addition many members of ECHAMP take measures to foster environmental protection and biodiversity.

ECHAMP members hold 22,000 registrations or authorisations, some 10% of which are varied each year. The regulatory environment challenges the sector's development, as it is incomplete and disproportionate to the wide range of starting materials and multiple safe finished products.

HAMPs have an important contribution to make to major EU health challenges - chronic disease, healthy ageing and antimicrobial resistance. Research confirms they add significant value to society, including comparative effectiveness, low incidence of side effects, cost-effectiveness, sustainable health and satisfied patients.

Contents

Introduction	2
Executive summary	4
Contents	5
Chapter 1 Industry development	7
1.1 Sales of HAMPs in the EU	7
Figure 1: Sales of HAMPs in the EU 1995 – 2013 (ex-factory prices)	7
1.2 Market trends	8
Figure 2: Market share of main markets for HAMPs in the EU, 2013	8
Figure 3: Growth of HAMPs in the CEEC markets 2005-2013 (€ million, ex-factory prices)	8
Figure 4: Anthroposophic medicinal products as a proportion of HAMPs in the EU (2013)	9
1.3 Relative size of the pharmaceutical sector	9
Chapter 2 The demand for homeopathic and anthroposophic medicinal products	11
2.1 Sales data as an indicator of demand	11
Figure 5: Sales of HAMPs per inhabitant in relation to GDP per capita in PPS (ex-factory 2013) (€)	11
2.2 Prescribers as an indicator of demand	12
Figure 6: Homeopathic prescribers per 100,000 inhabitants (2015)	12
Figure 7: Number of homeopathic prescribers compared to number of doctors in the EU (%)	13
2.3 Who uses homeopathy and anthroposophic medicine and why?	13
2.3.1 User awareness and use of HAMPs	13
2.3.2 Why homeopathic and anthroposophic medicinal products?	14
2.3.3 Portrait of frequent users	15
2.4 Need for information	15
Chapter 3 Profile of an industry	17
3.1 Economic profile	17
3.1.1 Employment	17
3.1.2 Company size	17
3.1.3 Regional distribution	18
3.1.4 Hybrid entrepreneurs: combining profitable and non-profitable business	18
3.1.5 A significant opportunity for pharmacies	18

3.2	Production	19
3.2.1	Diverse starting materials	19
3.2.2	Finished products	20
3.3	Environmental impact	21
3.3.1	Environmental impact of pharmaceuticals	21
3.3.2	Environmental impact of HAMPs	21
3.4	Co-operation with universities	22
Chapter 4	Added value of the sector	23
4.1	Comparative effectiveness	23
	Figure 8: Improvement over time of patients with a chronic disease with an average duration of 8 years, treated with homeopathic medicine	24
	Figure 9: Patients treated for acute respiratory and ear infections	25
4.2	Low incidence of side effects	25
4.3	Comparative cost-effectiveness	26
	Figure 10: Cost savings of homeopathy and anthroposophic medicine in relation to conventional medicine	27
4.4	Sustainable health and satisfied patients	27
Chapter 5	The legal and regulatory framework	29
5.1	Regulatory status of HAMPs in the EU	29
5.1.1	The legal framework	29
5.1.2	Implementation	30
5.2	Regulatory status – the experience of ECHAMP companies	31
Annex I:	Sales evolution of HAMPs by EU Member State (2010-2013)	33
Annex II:	Sales of HAMPs in relation to the total pharmaceutical market (2013)	34
Annex III:	Sales data in relation to GDP and PPS (2013)	35
Annex IV:	Prescribers of HAMPs in the EU (2015)	36
Annex V:	The implementation status of Article 16 (2) of Directive 2001/83/EC	37
About ECHAMP		38

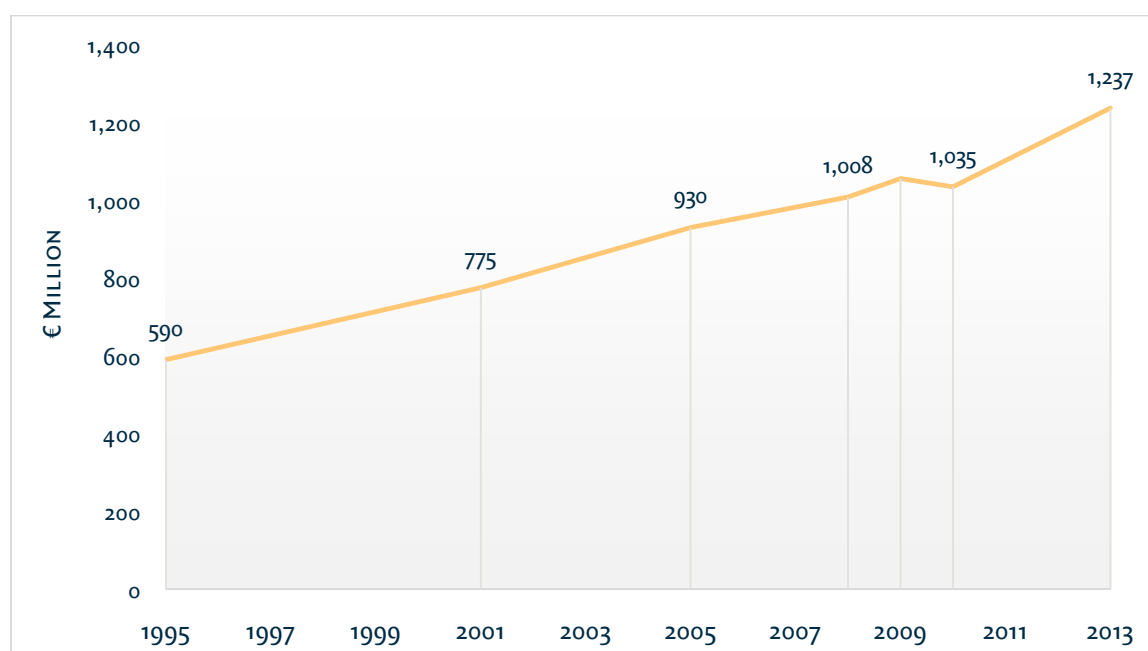
Chapter 1

Industry development

The market for homeopathic and anthroposophic medicinal products (HAMPs) was valued at €1,237 million in 2013 (ex-factory prices), representing 7% of the total EU market for non-prescription products. Average annual growth between 2010 and 2013 was 6.5%. This chapter presents new sales data for the industry, identifying a number of important trends. The data are compiled from market sources and an internal survey of ECHAMP members.

1.1 Sales of HAMPs in the EU

Between 2010 and 2013, the total turnover of HAMPs in the EU increased from €1,035 million to €1,237 million (ex-factory sales), representing growth of 19.5% over the period, or an average of 6.5% per year (see Annex I: Sales evolution of HAMPs by EU Member State 2010-13 and Figure 1). This shows positive market development compared to an average growth rate of 5% per year between 1995 and 2010, and a significant increase on sales development between 2009 and 2010, when sales declined by 2%.¹



Source: ECHAMP 2015

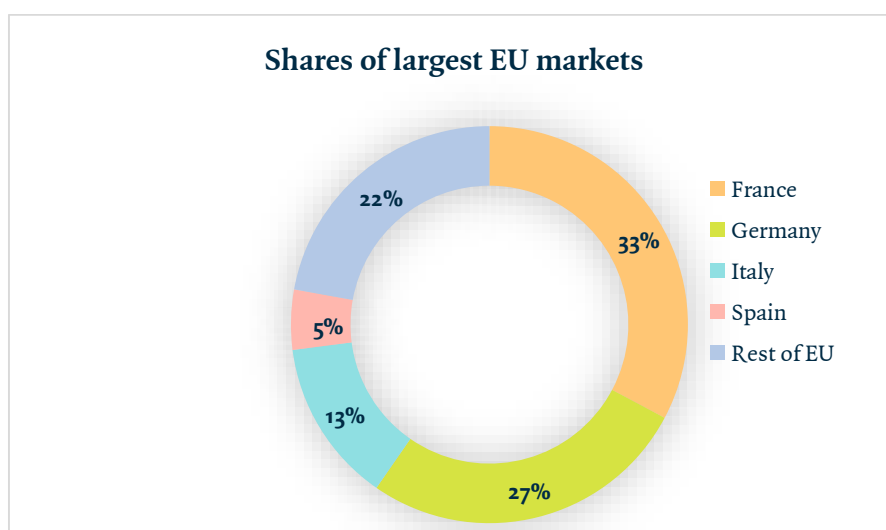
Figure 1: Sales of HAMPs in the EU 1995 – 2013 (ex-factory prices)

¹ Homeopathic and Anthroposophic Medicine in the EU - Facts and Figures 2011, ECHAMP 2011

This growth is thought to be due to the increasing professionalisation of marketing strategies in larger markets, the recovery from the global financial crisis of 2008 and the emergence of new markets.

1.2 Market trends

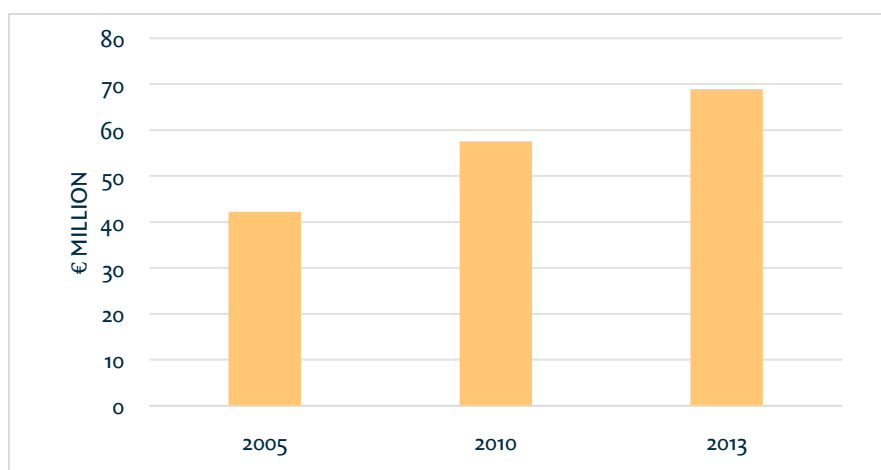
As in 2011, there are four large markets in the EU with a substantial tradition. France is the largest market, closely followed by Germany, and then Italy and Spain (see Figure 2). However, market size alone does not tell the full story on actual demand for these products, which can be made explicit in at least two thirds of EU Member States (see Chapter 2).



Source: ECHAMP 2015

Figure 2: Market share of main markets for HAMPs in the EU, 2013

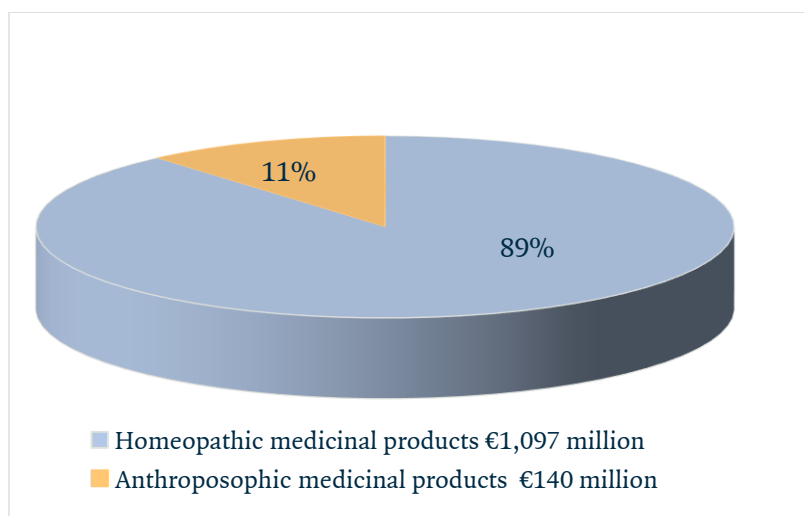
The four larger markets together grew by nearly 14% between 2010 and 2013, slightly faster than the overall growth in Western Europe of 13.5%. By contrast, the Central and Eastern Europe countries (CEEC) grew at a faster rate of nearly 20% in this period (see Figure 3), and their overall share of the EU market is now just over 6% (see Annex I).



Source: ECHAMP 2015

Figure 3: Growth of HAMPs in the CEEC markets 2005-2013 (€ million, ex-factory prices)

Sales of anthroposophic medicinal products have increased from €135m in 2010 to €140m in 2013, accounting for 11% of all HAMPs sales in 2013 (see Figure 4), although this share has decreased slightly from 13% in 2011.²



Source: ECHAMP 2015

Figure 4: Anthroposophic medicinal products as a proportion of HAMPs in the EU (2013)

1.3 Relative size of the pharmaceutical sector

The growth rate of 6.5% per year for the period 2010-2013 is slightly above the annual growth rate of 5.2% of the overall EU pharmaceutical sector during that period.³ The sales value of HAMPs represents 0.7% of total pharmaceutical sales in the EU.⁴ Countries in which the proportion of HAMPs sales in relationship to pharmaceutical sales is significantly above this average include France, Germany, Latvia, Lithuania and Bulgaria, demonstrating a higher than average penetration of these products, and countries where the share of HAMPs sales is slightly above or at about the average include Austria, Italy, Belgium and Netherlands (see Annex II: Sales of HAMPs in relation to the total pharmaceutical market 2013).

However, only about 2% of the value of the HAMPs market comes from products which are classed as prescription medicines,⁵ thus the vast majority of HAMPs are classed as non-prescription medicines and comparison with the market for non-prescription medicines is a more useful measure. In 2010, sales of HAMPs represented approximately 7% of the total EU market for non-prescription medicines.⁶

² Homeopathic and Anthroposophic Medicine in the European Union – Facts and Figures 2011, ECHAMP 2011

³ ECHAMP 2015, based on data from “The Pharmaceutical Industry in Figures”, EFPIA, 2010-2013

⁴ ECHAMP 2015, EFPIA <http://efpia.eu/facts-figures>

⁵ ECHAMP calculation based on information from members, 2015

⁶ ECHAMP calculation 2015 based on ECHAMP and AESGP data, 2013

IMS data show that, globally, ex-factory prices typically account for about 45% of total in-market sales figures in the pharmaceutical sector;⁷ this ratio is confirmed in the sector for HAMPs in the EU by experts in three major markets. Therefore some individual market comparisons are possible for 2013, and these show that in these major markets, HAMPs represent a significantly larger share of non-prescription medicines (consumer price) than the average: Germany 12%, Italy 15% and Spain 14%.⁸

⁷ www.imshealth.com/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Insights/Understanding_Pharmaceutical_Value_Chain.pdf

⁸ ECHAMP calculation 2015 based on ECHAMP data and AESGP data on non-prescription markets 2013 (consumer prices)

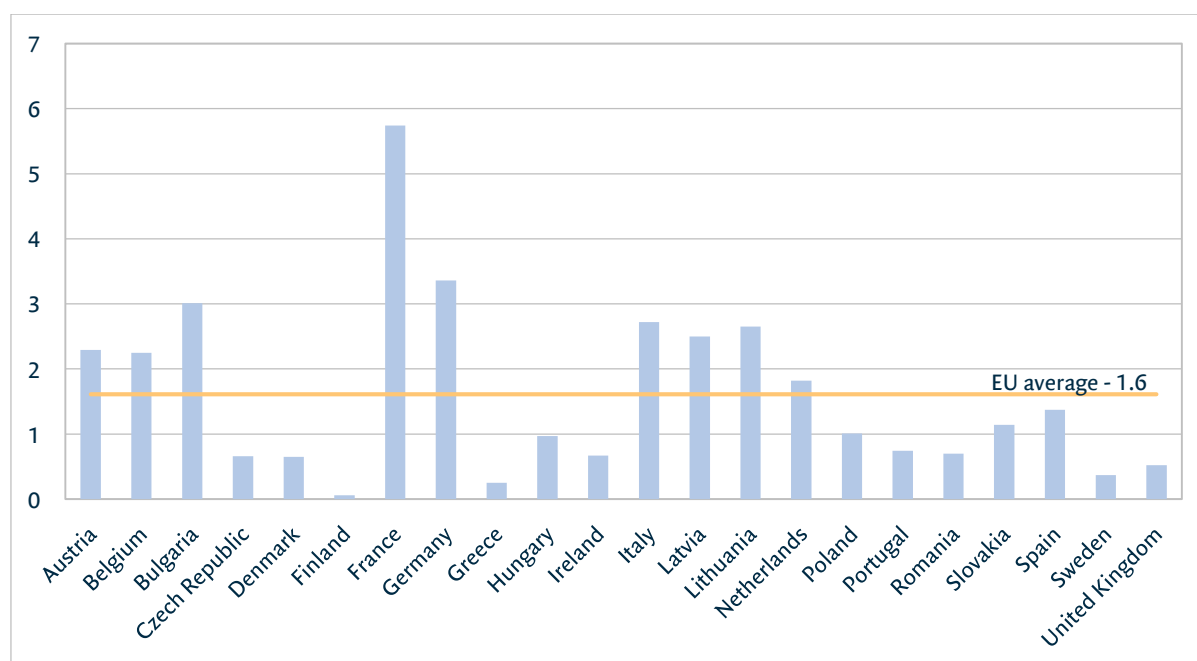
Chapter 2

The demand for homeopathic and anthroposophic medicinal products

There is a significant to high demand for homeopathic and anthroposophic medicinal products (HAMPs) in two thirds of EU Member States, including those both with and without a long-term tradition.⁹ This chapter seeks to quantify the demand for HAMPs in the EU markets in a variety of ways, and summarises market studies and other data to quantify and profile users.

2.1 Sales data as an indicator of demand

A comparison of sales per head of the population by market gives an indicator of relative demand for HAMPs. To ensure a consistent comparison, the data are adjusted to reflect national economic parameters - Gross Domestic Product (GDP) and Purchasing Power Standard (PPS). Figure 5 shows the adjusted sales of HAMPs per inhabitant (see Annex III: Sales data in relation to GDP and PPS).



Source: ECHAMP 2015

Figure 5: Sales of HAMPs per inhabitant in relation to GDP per capita in PPS (ex-factory 2013) (€)

⁹The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU, ECHAMP 2012

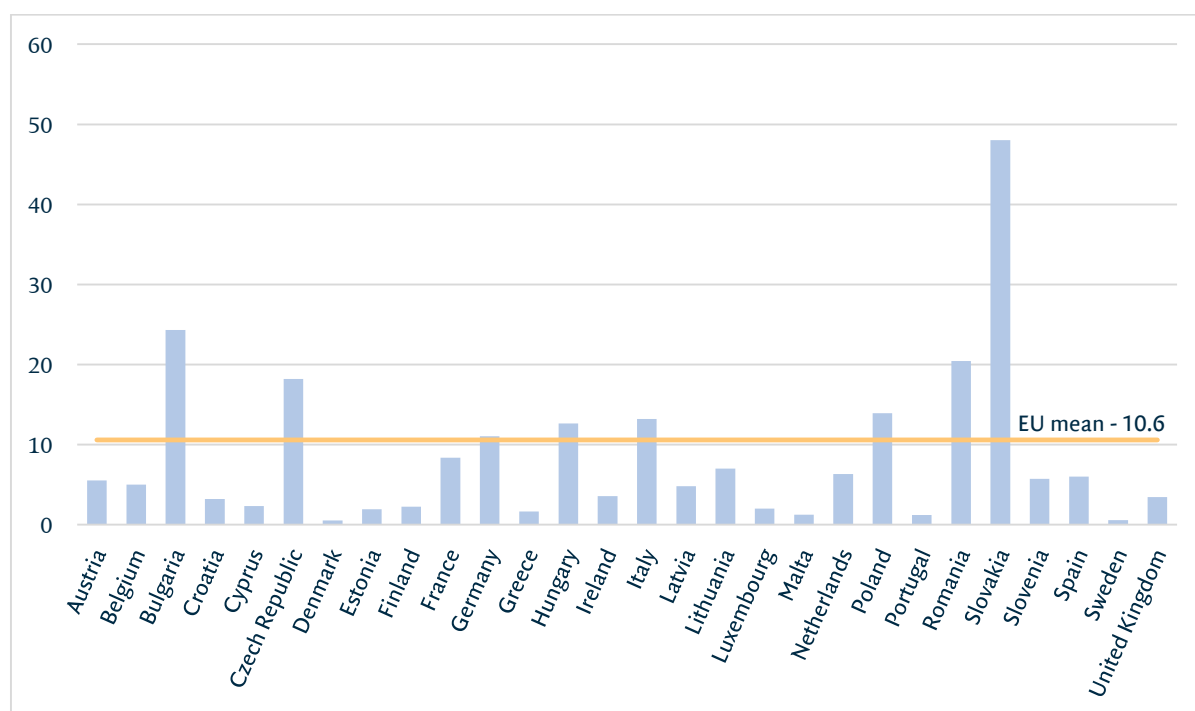
There are eight Member States, for which the adjusted sales are clearly higher than the European average: France, Germany, Bulgaria, Italy, Lithuania, Latvia, Austria and Belgium. These numbers demonstrate a clearly visible demand for HAMPs supported by availability of the products.

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

2.2 Prescribers as an indicator of demand

Figure 6 illustrates the number of homeopathic prescribers¹⁰ in relation to the respective population numbers in the Member States (see Annex IV: Prescribers of HAMPs in the EU). There are 10.6 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 Germany, Hungary, Italy and Poland are around about average.

These numbers compare to an average of about 345 practising doctors per 100,000 inhabitants in the EU.

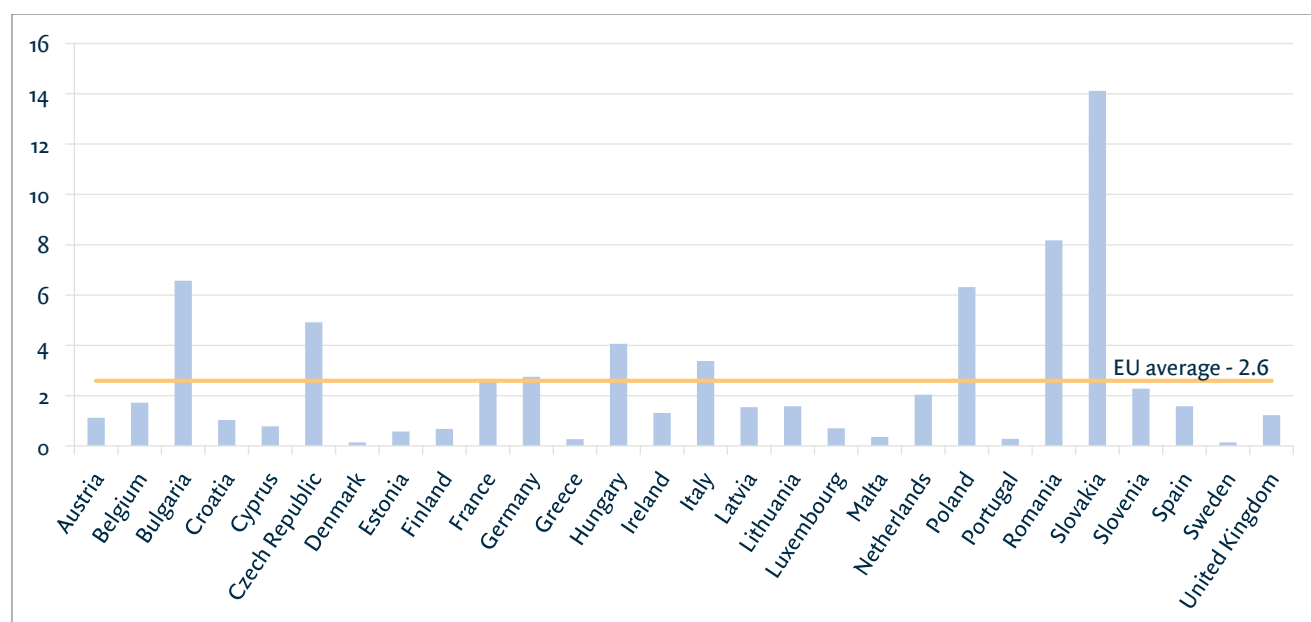


Source: ECHAMP 2015

Figure 6: Homeopathic prescribers per 100,000 inhabitants (2015)

¹⁰ 'Homeopathic prescribers' equals the sum of homeopathic doctors plus homeopathic practitioners (see Annex IV)

The number of homeopathic prescribers represents 2.6% of the total number of practising doctors in the EU (see Annex IV). Figure 7 relates the number of homeopathic prescribers to the number of practising doctors.



Source: ECHAMP 2015, OECD 2012

Figure 7: Number of homeopathic prescribers compared to number of doctors in the EU (%)

In Bulgaria, Czech Republic, Hungary, Italy, Poland, Romania and Slovakia, homeopathic prescribers represent a relatively high proportion of doctors, suggesting a higher than average demand for homeopathic medicine in these countries. By contrast, the two most established markets, France and Germany, have an average proportion of homeopathic prescribers compared to numbers of doctors.

Meanwhile, the number of anthroposophic doctors per 100,000 inhabitants has remained mostly stable for the past few years, with the exception of Germany, where there was a slight increase of anthroposophic doctors per 100,000 inhabitants (see Annex IV).

2.3 Who uses homeopathy and anthroposophic medicine and why?

2.3.1 User awareness and use of HAMPs

A 1998 European Commission study¹¹ reports 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.

¹¹ Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74, Com(97) 362 final

More recent market data 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 medicines and 60% have used them, up from 53% in 2009;¹²
- 82% of **Italians** have heard of homeopathy, 35% of Italian population have positive attitude towards homeopathy and 16% of them use homeopathy at least once a year;¹³
- 33% of **Spanish** people have used homeopathy, and 27% use it occasionally or regularly; eight out of ten (82%) people using homeopathy are satisfied or very satisfied with the outcome of their treatments, and this figure goes up to 99% in regular users;¹⁴
- 77% of **French** people trust homeopathy, 56% have used homeopathy and 36% use it on a regular basis;¹⁵
- 69% of **Belgian** households use homeopathic medicine,¹⁶ up from 50% in 2011. Among non-users of homeopathy, 70% state that they would like to use homeopathy in the future;
- 50% of **Austrians** have used homeopathic medicines, including 62% of women and 37% of men, and about 60% of families with young and school-age children.¹⁷

2.3.2 Why homeopathic and anthroposophic medicinal products?

Results of market 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;¹⁸
- 53% of **Italian** users do so because it is natural and non-toxic;¹⁹
- 57% of **Belgian** users choose homeopathy because it is natural and 41% do so to avoid chemical medicines;²⁰
- **Spanish** users choose homeopathy because of the absence of side effects, its effectiveness and safety during pregnancy.²¹

Research studies also confirm that users are attracted to homeopathy by its effectiveness and safe profile,²² its natural characteristics, and to avoid the adverse side effects of chemical products.²³

¹² Allensbach 2014

¹³ Doxapharma 2012

¹⁴ Estudio sobre conocimiento y uso de homeopatía en España, Revista Medica de Homeopatía, 2012

¹⁵ Boiron IPSOS 2012

¹⁶ Boiron 2013

¹⁷ IMS Health Austria, 2010; Homöopathische Einzelmittel werden statistisch nicht erfasst

¹⁸ Allensbach 2014

¹⁹ Doxapharma 2012

²⁰ Boiron 2013

²¹ Estudio sobre conocimiento y uso de homeopatía en España, Revista Medica de Homeopatía, 2012

²² 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

²³ 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

Patient satisfaction with anthroposophic healthcare is shown to be generally high and therapeutic expectations are fulfilled. In a recent Dutch survey, 2099 patients reported very high satisfaction with anthroposophic primary care practices.²⁴

2.3.3 Portrait of frequent users

Market studies show that users tend to be mostly female, educated and from the higher income brackets:

- in **Germany**, 73% of women have used homeopathy and 48% of men;²⁵
- in **Italy**, 71% of users are female, although only 60% of frequent users, and about half of users of homeopathy fall in the 25-44 age group; 70% are well or reasonably well-off and 75% have a further or higher education qualification;²⁶
- in **France**, 46% of women have used homeopathy in the past 12 months and 23% of men;²⁷
- in **Spain**, users tend to be women between the ages of 30 and 50.²⁸

One research study²⁹ confirms 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 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.³⁰

2.4 Need for information

Citizens express a wish for more support and information regarding complementary and alternative medicine (CAM) from the medical professionals. They need and want easily accessible and trustworthy information that can support an informed decision about treatment options.³¹

²⁴ Kienle et al, Anthroposophic Medicine: An Integrative Medical System Originating in Europe, Global Advances in Health and Medicine, Vol 2 No 5 November 2013

²⁵ Allensbach 2014

²⁶ Doxapharma 2012

²⁷ Boiron Ipsos 2012

²⁸ Estudio sobre conocimiento y uso de homeopatía en España, Revista Medica de Homeopatía, 2012

²⁹ 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

³⁰ 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

³¹ CAMbrella 2012

Word-of-mouth recommendation from friends and family is still the main reason users try homeopathy, although recommendations from doctors and pharmacists are also important.

Market surveys 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 the pharmacist;³²
- in **Italy**, 31% of users were first recommended a homeopathic medicine by a specialist, 23% by a friend or family member, 22% by their general practitioner and 16% by a pharmacist;³³
- 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,³⁴ although 36% of Belgians also turn to the internet for information;³⁵
- a similar picture in **Spain**: 53% of Spanish people have heard about homeopathy from friends or family, and 21% from their pharmacist or doctor.³⁶

³² Allensbach 2014

³³ Doxapharma 2012

³⁴ Boiron 2013

³⁵ Ipsos Boiron 2011

³⁶ Estudio sobre conocimiento y uso de homeopatía en España, Revista Medica de Homeopatía, 2012

Chapter 3

Profile of an industry

Europe is the global centre of expertise for homeopathic and anthroposophic medicinal products (HAMPs) and the industry is unique in the level of complexity it manages on a daily basis. It sources thousands of mostly natural starting materials and produces a multitude of distinct finished products with different potencies and dosage forms, balancing a significant proportion of non- or low-profit products within its business models. This section profiles the industry in detail. The data are drawn from the results of a survey of ECHAMP members, carried out in the first half of 2015, and other referenced sources.

3.1 Economic profile

3.1.1 Employment

The sector employs about 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. The figure has increased by 25% since 2010.

This growth is reflected in substantial capital investment by many of the ECHAMP members over the same period.

3.1.2 Company size

The five largest companies in the sector represent approximately 60-70% of the total sector turnover; the remaining 30-40% of the industry is characterised by a large number of small and medium-sized companies (SMEs).³⁷ ECHAMP is the only organisation representing this sector at an international or European level, with 44 member companies of all sizes.

According to the European Commission's definition, ECHAMP's members can be categorised as follows:

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

³⁷ Enterprise and Industry, European Commission: http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm

3.1.3 Regional distribution

ECHAMP's members are drawn from 18 different EU countries. However, 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',³⁸ the highly industrialised regions of the Rhône-Alpes region in France, the Lombardy region in Italy, Catalonia region 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.³⁹

3.1.4 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.⁴⁰ Prescribers have expressed a need for 3,000 distinct stocks for the proper practice of these therapies⁴¹ 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.

3.1.5 A significant opportunity for pharmacies

98% of the turnover of HAMPs comes from products with a regulatory status of non-prescription medicines.⁴² Pharmacies remain the main channel for the sale of HAMPs – in Italy, for example, 87% of Italians purchase their homeopathic medicines in the pharmacy.⁴³ Almost 86% of HAMPs are sold with a direct user-pharmacy contact in Germany.⁴⁴ IMS data show that globally, ex-factory prices typically account for about 45% of total in-market sales figures in the pharmaceutical sector;⁴⁵ this ratio is confirmed in the sector for HAMPs in the EU by experts in three major markets.

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); over 26% of Italians think

³⁸ www.4motors.eu

³⁹ Bedeutung der Komplementärmedizin mit Fokus auf Homöopathie und Anthroposophische Medizin in Baden-Württemberg, Kern, 2015

⁴⁰ Low profit or non-profit margin products mean their profits are equal or less than zero

⁴¹ 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

⁴² ECHAMP calculation based on member information, 2015

⁴³ Doxapharma 2012

⁴⁴ ECHAMP calculation – data from Der Arzneimittelmarkt in Deutschland, Zahlen und Fakten, Bundesverband der Arzneimittel Hersteller (BAH) e.V., 2015

⁴⁵ www.imshealth.com/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Insights/Understanding_Pharmaceutical_Value_Chain.pdf

pharmacists should be able to provide the information they need about these medicinal products.⁴⁶

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. Educated pharmacists are better able to support their customers' choices. Investment in the pharmacy sector therefore focuses on providing information and training, with significant results. There are companies who invest up to 30% of their marketing budget in pharmacy training, achieving 20% sales growth. The general trend towards over-the-counter medicines also applies to HAMPs. Pharmacies have a clear role to play.

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

- this growing market reflects the 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.

3.2 Production

The ECHAMP member companies all operate according to pharmacopoeia and good manufacturing practice standards.

Europe is the centre of pharmaceutical expertise in these products. The pharmaceutical processes, including quality monographs for both starting materials and manufacturing methods, are developed in the industry, further developed with academics 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.), as well as in the private 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.

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.

3.2.1 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.

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

⁴⁶ Doxapharma 2012

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.

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%.

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 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.

In order to guarantee the quality and availability of botanical starting materials, one third of surveyed manufacturers have developed their own medicinal gardens. About 30% of companies who do not yet have a medicinal garden express an interest in having one in the future.

3.2.2 Finished products

The HAMPs sector offers a very high number of distinct finished products – the ECHAMP member companies market 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 100 million units of finished products are produced for EU markets each year. Assuming that companies match production with demand, 100 million units reflect the demand of the citizens.

The multitude of finished medicinal products of smallest batch sizes clearly differentiates the sector from the conventional 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.

In addition, 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.

3.3 Environmental impact

3.3.1 Environmental impact of pharmaceuticals

The environmental impact of pharmaceuticals is being studied in the context of global environmental responsibility as the pollution of water and soil with pharmaceutical residues is an emerging environmental concern. There are more than 10,000 tonnes of antibiotics consumed in Europe each year,⁴⁷ with 30-90% passing through animals and humans completely unchanged. These reach the sea via hospitals, municipal sewage, fish farms and run-off from agriculture and landfills and many different human pharmaceuticals are found to be present in effluents of sewage treatment works.⁴⁸

Health and environmental regulators, academics and the pharmaceutical industry are working to assess the situation and find solutions. The European Commission has been asked to develop a strategic approach to pollution of water by pharmaceutical substances by the end of 2015,⁴⁹ to help guard against the spread of antibiotic resistance, protect wildlife and improve transparency in the industry.⁵⁰

3.3.2 Environmental impact of HAMPs

HAMPs have negligible environmental impact. 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,⁵¹ which exclude the use of synthetic fertilizers and chemical plant protection agents during the production, as well as artificial additives during processing, complying with EU standards for organic farming. In addition, these require specific measures to strengthen life processes in soil and foodstuffs. The practice of biodynamic agriculture preserves nature, increases soil fertility, and enhances biodiversity.⁵²

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,⁵³ Demeter –

⁴⁷ University of Gothenburg, Antibiotic contamination a threat to humans and the environment, 8 August 2012: http://science.gu.se/english/News/News_detail/antibiotic-contamination-a-threat-to-humans-and-the-environment.cid1091767

⁴⁸ https://en.wikipedia.org/wiki/Environmental_impact_of_pharmaceuticals_and_personal_care_products

⁴⁹ http://ec.europa.eu/health/human-use/environment-medicines/index_en.htm

⁵⁰ http://ec.europa.eu/environment/integration/research/newsalert/pdf/new_controls_reduce_environmental_risks_pharmaceuticals_antibiotics_422na1_en.pdf

⁵¹ www.demeter.net/what-is-demeter/this-is-demeter

⁵² Organic farming enhances soil fertility and biodiversity, FIBL, 2000

⁵³ www.ecocert.com/en

certification for biodynamic agriculture,⁵⁴ Oko-Bio,⁵⁵ EU-Organic⁵⁶ 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,⁵⁷ Member of Organic Trust,⁵⁸ ISO 14001, certification for environmental management and EMAS, Eco-Management and Audit Scheme.⁵⁹

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 Bioproducts (UEBT),⁶⁰ which ensures manufacturers' procurement to support biodiversity, respect traditional knowledge and guarantee fair remuneration of all partners throughout the supply chain.

3.4 Increasing co-operation with universities

HAMPs have an established tradition and long-standing use; at the same time, they take part in the debates and requirements of modern science, and are increasingly the subject of basic as well as clinical research.⁶¹ A trend towards increasing co-operation with the academic sector can be perceived amongst ECHAMP members, half of whom foster co-operations with universities. Academic topics range from clinical aspects to pharmaceutical development.

⁵⁴ www.demeter.net/

⁵⁵ www.stwno.de/joomla/en/gastro-en/products-en/bio-certification-en

⁵⁶ http://ec.europa.eu/agriculture/organic/downloads/logo/index_en.htm

⁵⁷ <https://um.baden-wuerttemberg.de/de/wirtschaft/betrieblicher-umweltschutz/foerdermoeglichkeiten/foerderprogramm-ecofit/>

⁵⁸ <http://organictrust.ie/>

⁵⁹ http://ec.europa.eu/environment/emas/index_en.htm

⁶⁰ <http://ethicalbioproducts.org/>

⁶¹ See Homeopathy Research Institute, www.hri-research.org

Chapter 4

Added value of the sector

Homeopathy and anthroposophic medicine and their related products have an important contribution to make to major EU health challenges. Research in these fields confirms significant added value to society. These include:

- comparative effectiveness
- low incidence of side effects
- comparative cost-effectiveness
- sustainable health and satisfied patients.

Homeopathic and anthroposophic medicinal products (HAMPs) also have a role to play in fields of critical relevance to EU health policy, such as chronic disease, healthy ageing and antimicrobial resistance.

4.1 Comparative effectiveness

As of May 2015, there were 1117 clinical trials of homeopathy, 298 of which were randomized controlled trials.⁶² Up to the end of 2014, there were 189 peer-reviewed papers, with useable data, that reported randomised controlled trials (RCTs) in homeopathy. Of these, 104 papers were placebo-controlled - 41% reported positive findings, 5% were negative and 54% were non-conclusive.⁶³ The percentages of positive, negative and inconclusive findings are similar in conventional medicine.⁶⁴

In addition, there have been five systematic reviews on homeopathy as a whole⁶⁵ (including all conditions), four of which have been positive and one negative. Research demonstrates positive results for a number of specific conditions: allergies and upper respiratory tract infections, seasonal allergic rhinitis, childhood diarrhoea, post-operative ileus, rheumatic diseases and vertigo. Most recently, a new, high quality, scientifically robust systematic review on homeopathy shows that individualised homeopathic treatment is 1.5 to two times more likely to have a beneficial effect than placebo.⁶⁶

⁶² www.carstens-stiftung.de/core-hom

⁶³ <http://facultyofhomeopathy.org/randomised-controlled-trials/>

⁶⁴ www.hri-research.org/resources/homeopathy-the-debate/there-is-no-scientific-evidence-homeopathy-works/

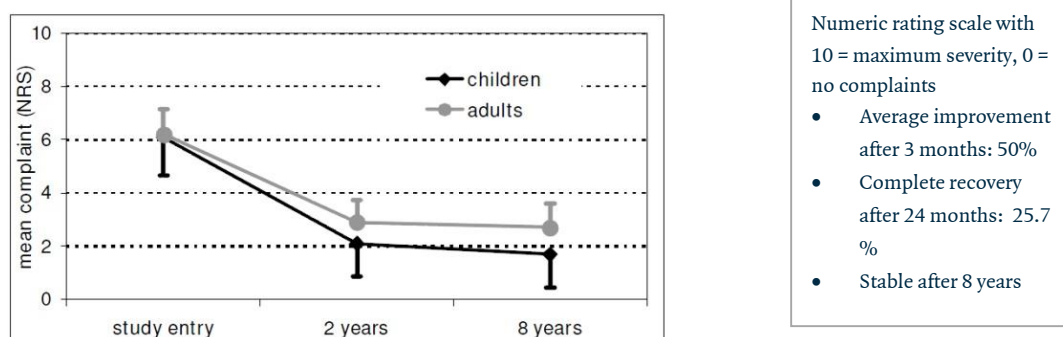
⁶⁵ <http://facultyofhomeopathy.org/research/systematic-reviews-of-rcts/>

⁶⁶ Mathie et al., Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis, *Systematic Reviews* 2014, 3:142

The most recent comprehensive systematic review of clinical studies of anthroposophic medicine treatment included a total of 256 studies.⁶⁷ 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 in real life clinical situations have shown that homeopathy can produce results as good as or better than conventional medicine.⁶⁸

For example, 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 8 years (see Figure 8).⁶⁹



Source: Witt et al., 2008

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

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 9);⁷⁰ similar results were obtained for homeopathy,⁷¹ one study showing lower use of antibiotics and fewer antipyretic/anti-inflammatory drugs for a similar evolution.⁷²

⁶⁷ Kienle et al., 2006, 2011

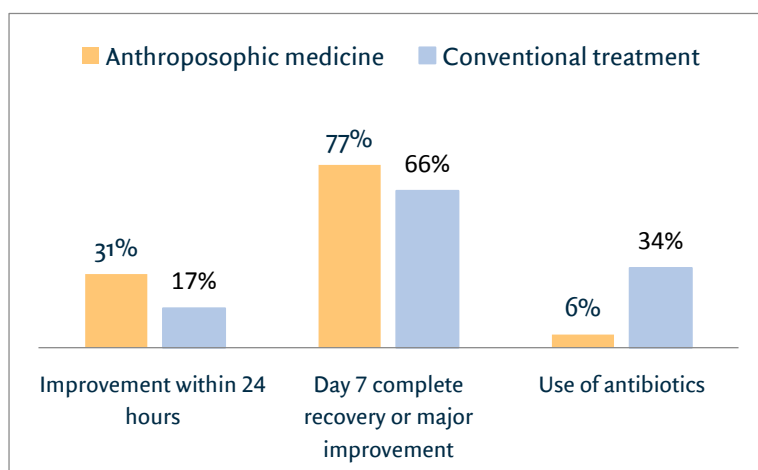
⁶⁸ www.hri-research.org

⁶⁹ 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

⁷⁰ 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;

⁷¹ IIPCOS study, Haidvogel, 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.

⁷² 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



Source: Hamre et al.(2005)

Figure 9: Patients treated for acute respiratory and ear infections

4.2 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. There was a 44% increase of adverse reactions (70,000 adverse cases) in the European Economic Area (EEA) between 2011 and 2013.⁷³ In addition, each year about 4.1 million people in the EU acquire an infection whilst receiving health care, often resulting from inappropriate use of antibiotics. This resistance results in 25,000 deaths per year.⁷⁴

In this context, HAMPs have an important role to play, as they can generally be regarded as safe. For example:

- a systematic review of the safety of homeopathy⁷⁵ 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^{76,77} 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;

⁷³ 2013 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission (European Medicine Agency): www.ema.europa.eu/docs/en_GB/document_library/Report/2014/04/WC500165780.pdf

⁷⁴ European Commission, Public Health, page 8:

http://ec.europa.eu/health/health_policies/docs/improving_health_for_all_eu_citizens_en.pdf

⁷⁵ Dantas F, Rampes H (2000). Do homeopathic medicines provoke adverse effects? A systematic review. *British Homeopathic Journal*, 89 (Suppl 1):S35–S38

⁷⁶ 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

⁷⁷ Endrizzi C, Rossi E, Crudeli L, Garibaldi D (2005). Harm in homeopathy: aggravations, adverse drug events or medication errors? *Homeopathy*, 94:233–240

- other studies confirm the safety, showing that that when applied properly, classical homeopathy has few side-effects and the use of high-potencies is free from toxic effects;^{78,79}
- 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.⁸⁰

4.3 Comparative 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.⁸¹

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;⁸²
- 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;⁸³
- an Italian study⁸⁴ 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;⁸⁵

⁷⁸ Stub et al., Risk in homeopathy - Classification of adverse events and homeopathic aggravations, Complementary Therapies in Medicine, 2015

⁷⁹ Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Costs. Gudrun Bornhöft & Peter F. Matthiessen (Editors), 2011

⁸⁰ 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

⁸¹ Reducing healthcare costs with homeopathy and anthroposophic medicine: A summary of available literature, ECHAMP 2014

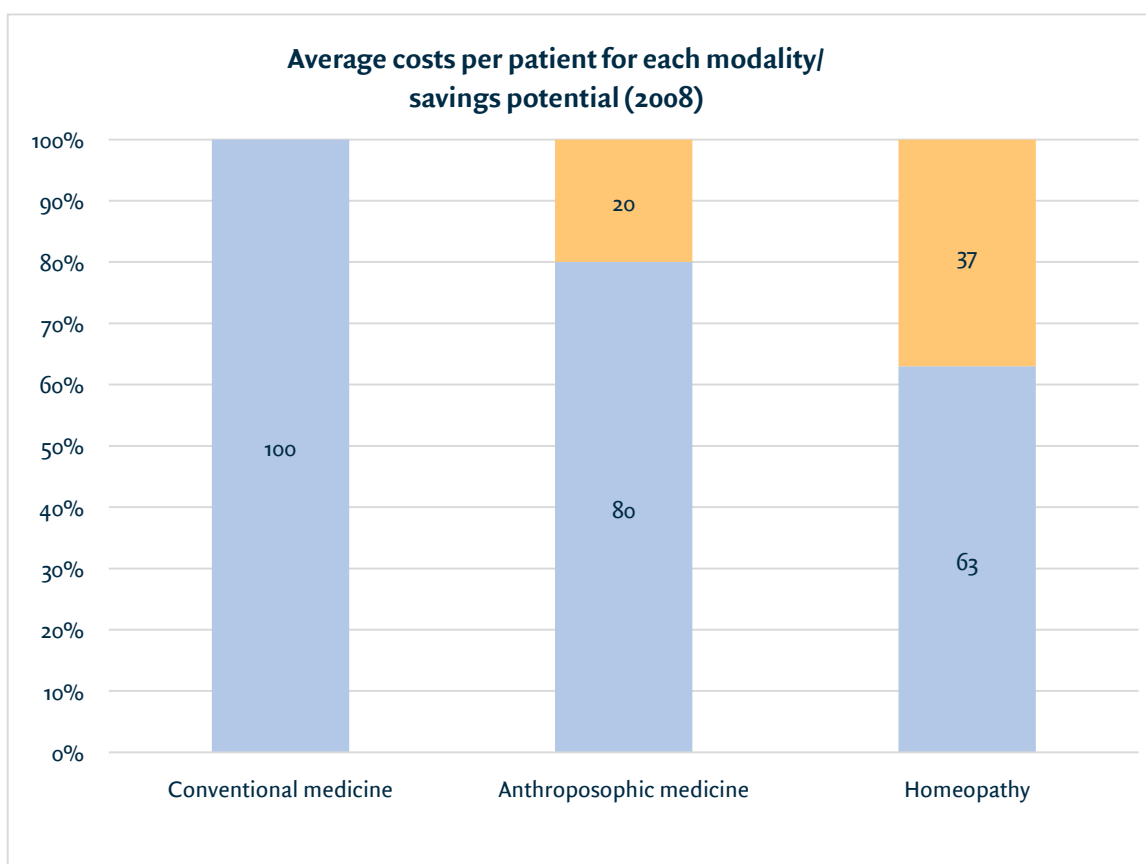
⁸² Witt et al: Outcome and costs of homoeopathic and conventional treatment strategies: a comparative cohort study in patients with chronic disorders. Complement Ther Med. 2005 Jun;13(2):79-86

⁸³ Economic impact of homeopathic practice in general medicine in France, Health Econ Review, 2015; 5: 18, 8 Jul 2015

⁸⁴ Rossi et al., Cost-benefit evaluation of homeopathic v conventional therapy in respiratory diseases Homp (2009) 98:2-10

⁸⁵ Trichard M et al., Pharmacoeconomic comparison between homeopathic and antibiotic treatment strategies in recurrent acute rhinopharyngitis in children. Homeopathy 2005;94:3-9

- Swiss insurance company data show that homeopathic and anthroposophic medicines offer **potential savings of 37% and 20% respectively compared to conventional medicines**⁸⁶ (see Figure 10).



Source: Santésuisse 2008

Figure 10: Cost savings of homeopathy and anthroposophic medicine in relation to conventional medicine

4.4 Sustainable health and satisfied patients

A number of studies demonstrate a high level of patient satisfaction with homeopathic and anthroposophic medicine treatment.

Specifically:

- one observational study⁸⁷ 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;

⁸⁶ Santésuisse, Datapool, Swiss insurance companies, 2008

⁸⁷ An observational study of patients receiving homeopathic treatment, Van Wassenhoven M. and Ives G., 2004: <http://www.ncbi.nlm.nih.gov/pubmed/14960096>

- 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%**;⁸⁸
- 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;⁸⁹
- similarly, patients report very high satisfaction with anthroposophic healthcare; patient satisfaction is generally high and therapeutic expectations are fulfilled.⁹⁰

The quoted studies suggest that the development of integrative medicine, including homeopathy and anthroposophic medicine, is a rational and sustainable trend.

⁸⁸ Patient satisfaction and side effects in primary care: An observational study comparing homeopathy and conventional medicine, Biomedcentral, 18 September 2008: <http://www.biomedcentral.com/1472-6882/8/52>

⁸⁹ Spence et al., Homeopathic treatment for chronic disease: a 6-year university-hospital outpatient observational study. *Journal of Alternative and Complementary Medicine*, 2005; 5: 793–798

⁹⁰ Kienle et al., *Anthroposophic Medicine: An Integrative Medical System Originating in Europe*, *Global Advances in Health and Medicine*, Vol 2 No 5, 2013

Chapter 5

The legal and regulatory framework

The regulatory environment for homeopathic and anthroposophic medicinal products (HAMPs) is incomplete and this challenges the sector development. The overall regulatory environment, including assessment capacity and policy at national level, is disproportionate to the large range of starting materials and multiple finished medicinal products which are used in homeopathy and anthroposophic medicine.

5.1 Regulatory status of HAMPs in the EU

5.1.1 The legal framework

The registration for a homeopathic medicinal product to be present on the market in the EU is regulated by specific provisions in Directive 2001/83/EC on medicinal products for human use, completed with specific provisions on the proof of quality and safety in Directive 2003/63/EC.

The overall picture for the regulatory status of anthroposophic medicinal products in the EU is fragmented; Directive 2001/83/EC Article 1.5, as enlarged by 'Recital 22,' defines that the legal basis of homeopathic medicinal products applies equally to all anthroposophic medicinal products that are homeopathically manufactured. There is no special legal provision for anthroposophic medicinal products which are not manufactured according to homeopathic manufacturing methods. Depending on the kind of active substances, the indication, the long-standing use and the available clinical data, the provisions for traditional herbal medicinal products or for well-established use may be an option. A number of limitations exclude the large majority of anthroposophic medicinal products from these specific license types.

Directive 2001/83/EC on medicinal products for human use outlines two procedures for market access of homeopathic and homeopathically-produced anthroposophic medicinal products:

- Special Simplified Registration Procedure (Article 14);
- Marketing Authorisation (Article 16).

The Special Simplified Registration Procedure (simplified registration) applies to homeopathic medicinal products that comply with the following criteria:

- they are administered orally or externally;
- no specific therapeutic indication appears on their labelling;
- there is a sufficient degree of dilution to guarantee their safety; in particular they may not contain more than 1 part per 10,000 of the mother tincture or more than 1:100th of the

smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

Those products which do not comply with these criteria need to be authorised in accordance with Article 16. As a consequence, the general marketing authorisation procedures for allopathic medicinal products are in principle applicable to homeopathic medicinal products which are not eligible for a simplified registration.

However, Member States have the competence under Article 16(2) to retain or introduce specific rules for pre-clinical tests (pharmacological and toxicological tests) and clinical trials in accordance with the principles and characteristics of homeopathy as practised in that particular Member State.

5.1.2 Implementation

The status of implementation of Directive 2001/83/EC varies considerably in the 28 Member States of the EU (see Annex V: The implementation status of Article 16 (2) of Directive 2001/83/EC).

Since the implementation of Article 14 (simplified registration) became mandatory after the extensive revision of Directive 2001/83/EC in 2003/4, the legal and regulatory provisions for the special simplified registration procedure have been implemented in all 28 Member States. The same applies to the option to make an application for such a registration in more than one Member State at once, by means of mutual recognition, in accordance with Articles 28 and 29 (1-3) of Directive 2001/83/EC.

However, according to Directive 2001/83/EC, the implementation of Article 16.2 (marketing authorisation of homeopathically manufactured medicinal products) is optional for a Member State. Article 16.2 foresees that a Member State may establish specific national rules for pre-clinical tests and clinical trials.

There are currently twelve Member States which have introduced Article 16.2, including the publication of specific rules for preclinical tests and clinical trials. In six Member States, Article 16.2 has not been implemented at all; in these countries Article 16.1 (full marketing authorisation in accordance with Articles 8, 10, 10a, b, c and 11) applies for homeopathic medicinal products. In ten Member States, the optional Article 16.2 is given in the national medicines law but no specific rules for pre-clinical and clinical testing are provided. This means that in practice in these countries Article 16.2 cannot be considered as implemented.

In addition, Article 13 of Directive 2001/83/EC allows Member States to keep on the national market homeopathic medicinal products which are covered by a license granted in accordance with national legislation on or before 31 December 1993.

5.2 Regulatory status – the experience of ECHAMP companies

ECHAMP member companies:⁹¹

- hold 21,793 national registrations of authorisations for HAMPs;
- have a further 1774 registrations or authorisations pending;
- expect numbers of registrations or authorisations to increase in the coming years (60% of respondents) by an anticipated 10%;
- processed 2196 variations in 2014;
- expect numbers of variations to increase in the coming years (55% of respondents) by about 7%.

The number of registrations is comparably high in Austria, Czech Republic, France, Germany, Hungary, the Netherlands, Slovakia and Portugal. It is comparably low in Belgium, Denmark, Finland, Ireland and Romania.

The regulatory environment for HAMPs is still incomplete and this challenges the sector development.⁹² In those countries where there is a clear consumer demand, and Article 16.2 is not implemented or enforced, availability is limited. At the same time, in countries where it has been implemented, it is a disproportionate burden to companies in terms of dossier maintenance and finance.

The overall regulatory environment, including assessment capacity and policy at national level, is not proportionate to the large range of starting materials and multiple finished medicinal products which are used in homeopathy and anthroposophic medicine. In many Member States the number of registered products poorly reflects the high numbers of homeopathic prescribers.

Availability of these products is threatened in some Member States by the lack of a registration process, and in others by an incomplete process for the renewal of existing registrations. The regulatory burden is such that it is not sustainable to maintain registrations for the full range of medicinal products required for proper practice of these therapies.

The ECHAMP report ‘The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU’ (2012) concludes:

- there is a lack of full transparency as regards the regulatory status of homeopathic and anthroposophic medicinal products in the EU Member States;
- the enforcement of Directive 2001/83/EC, as implemented in the legislation of the Member States, is far from complete for either Articles 14 or 16.2, more than twenty years after the publication of the specific Directive 92/73/EEC on homeopathic medicinal products, consolidated within Directive 2001/83/EC in 2001;

⁹¹ ECHAMP member survey 2015

⁹² The Availability of Homeopathic and Anthroposophic Medicinal Products, ECHAMP 2012

- the introduction of the Mutual Recognition/Decentralised Procedure in 2004/5 has failed to solve the problem of the huge amount of work and duplication of effort; this is mainly due to the disproportionate efforts linked to the execution of such procedures;
- the presence of anthroposophic medicinal products on the market and their national authorisation or registration in some Member States are related to national policy already in place before the publication of the specific homeopathic Directive in 1992.

In order to ensure sustainable development of the sector and provide patients in the EU with freedom of choice as regards these medicines, it is necessary to further develop the regulatory environment, so as to match the regulatory requirements with the actual characteristics of the products and the sector.

Annex I: Sales evolution of HAMPs by EU Member State 2010-2013

(Ex-factory, € thousand)

Country	2005	2010	2013	% growth 2010 to 2013
AUSTRIA	20,100	22,412	24,900	11%
BELGIUM	35,341	32,974	30,000	-9%
BULGARIA	-	5,140	9,907	93%
CZECH REPUBLIC	2,046	3,416	5,637	65%
DENMARK	1,873	4,410	4,500	2%
FINLAND	253	-	341	-
FRANCE	294,000	322,565	402,560	25%
GERMANY	267,782	302,060	329,800	9%
GREECE	385	-	2,000	-
HUNGARY	3,870	5,338	6,352	19%
IRELAND	2,435	1,575	4,000	154%
ITALY	136,991	166,599	163,615	-2%
LATVIA	2,388	3,138	3,206	2%
LITHUANIA	2,800	6,378	5,800	-9%
NETHERLANDS	56,465	31,663	40,000	26%
POLAND	29,773	30,309	25,863	-15%
PORTUGAL	3,567	5,372	6,047	13%
ROMANIA	-	2,009	7,519	274%
SLOVAKIA	1,325	1,733	4,611	166%
SPAIN	35,363	48,306	60,000	24%
SWEDEN	3,000	3,800	4,570	20%
UNITED KINGDOM	31,349	34,956	36,399	4%
For EU-28	931,106	1,034,779	1,236,650	19.5%

Source: ECHAMP 2015

Annex II: Sales of HAMPs in relation to the total pharmaceutical market (2013)

Countries	Total market HAMPs 2013 ex-factory prices (€ million)	Total market pharma 2013 ex-factory prices (€ million)	Sales of HAMPs in relation to total pharma market in 2013 (%)
AUSTRIA	24.90	3,207	0.78
BELGIUM	30.00	4,432	0.68
BULGARIA	9.90	853	1.16
CROATIA	-	647	-
CYPRUS	-	198	-
CZECH REPUBLIC	5.64	2,125	0.27
DENMARK	4.50	2,095	0.21
ESTONIA	-	231	-
FINLAND	0.34	2,114	0.02
FRANCE	402.56	26,744	1.51
GERMANY	392.80	26,960	1.22
GREECE	2.00	3,949	0.05
HUNGARY	6.35	2,010	0.32
IRELAND	4.00	1,788	0.22
ITALY	163.61	20,941	0.78
LATVIA	3.20	310	1.03
LITHUANIA	5.80	467	1.24
LUXEMBOURG	-	-	-
MALTA	-	77	-
NETHERLANDS	40.00	4,471	0.89
POLAND	25.86	5,347	0.48
PORTUGAL	6.05	2,804	0.22
ROMANIA	7.52	2,659	0.28
SLOVAKIA	4.61	1,166	0.40
SLOVENIA	-	507	-
SPAIN	60.00	13,203	0.45
SWEDEN	4.57	3,653	0.13
UNITED KINGDOM	36.40	16,671	0.22
EU – 28 total	1,237	149,639	

Source: ECHAMP 2015, EFPIA 2015

Annex III: Sales data in relation to GDP and PPS (2013)

Countries	Population 2013 (million people)	GDP per capita 2013 (adjusted for PPS- Purchasing Power Standard)	Market HAMPs: 2013 ex- factory prices (€ million)	Sales of HAMP per inhabitant 2013 (€)	Sales of HAMPs per inhabitant in relation to GDP per capita expressed in PPS (€)
AUSTRIA	8.5	128	24.90	2.93	2.29
BELGIUM	11.2	119	30.00	2.68	2.25
BULGARIA	7.3	45	9.90	1.36	3.01
CROATIA	4.3	-	-	-	-
CYPRUS	0.9	89	-	-	-
CZECH REP	10.5	82	5.64	0.54	0.66
DENMARK	5.6	124	4.50	0.80	0.65
ESTONIA	1.3	73	-	-	-
FINLAND	5.4	113	0.34	0.06	0.06
FRANCE	65.6	107	402.56	6.14	5.74
GERMANY	80.5	122	329.80	4.10	3.36
GREECE	11.0	73	2.00	0.18	0.25
HUNGARY	9.9	66	6.35	0.64	0.97
IRELAND	4.6	130	4.00	0.87	0.67
ITALY	60.8	99	163.61	2.69	2.72
LATVIA	2.0	64	3.20	1.60	2.50
LITHUANIA	3.0	73	5.80	1.93	2.65
LUXEMBOURG	0.5	258	-	-	-
MALTA	0.4	86	-	-	-
NETHERLANDS	16.8	131	40.00	2.38	1.82
POLAND	38.1	67	25.86	0.68	1.01
PORTUGAL	10.5	78	6.05	0.58	0.74
ROMANIA	20.0	54	7.52	0.38	0.70
SLOVAKIA	5.4	75	4.61	0.85	1.14
SLOVENI	2.1	82	-	-	-
SPAIN	46.7	94	60.00	1.28	1.37
SWEDEN	9.6	127	4.57	0.48	0.37
UNITED KINGDOM	64.3	109	36.40	0.57	0.52
EU-28 total	505.1	-	1237.02	-	-
Mean EU-27	502.6	100	-	-	-
EU total (21 Member States)	-	-	1034.88	1.53	1.61

Source: ECHAMP 2015, EUROSTAT 2015

Annex IV: Prescribers of HAMPs in the EU (2015)

COUNTRIES	Total no. of homeo- pathic prescribers 2015	Homeo- pathic prescribers per 100,000 inhabitants 2015	Practising doctors per 100,000	% homeo- pathic prescribers/ practising doctors per 100,000 inhabitants	Number of anthropo- sophic doctors	Number of anthropo- sophic doctors per 100,000 inhabitants
AUSTRIA	470	5.5	490	1.13%	11-110	0.1-1.2
BELGIUM	562	5.0	290	1.73%	11-110	0.1-0.9
BULGARIA	1775	24.3	370	6.57%	<10	<0.1
CROATIA	130	3.02	290	0.24%	-	-
CYPRUS	21	2.3	300	0.78%	0	0
CZECH REP	1913	18.2	370	4.92%	11-110	0.1-1.0
DENMARK	30	0.5	350	0.15%	11-110	0.2-1.8
ESTONIA	25	1.9	330	0.58%	11-110	0.8-7.7
FINLAND	122	2.3	330	0.68%	11-110	0.2-1.8
FRANCE	5500	8.4	330	2.54%	101-1000	0.2-1.5
GERMANY	8879	11.0	400	2.76%	>1088	>1.3
GREECE	181	1.6	620	0.27%	0	0
HUNGARY	1250	12.6	310	4.07%	<10	<0.1
IRELAND	164	3.6	270	1.32%	<10	<0.2
ITALY	8020	13.2	390	3.38%	101-1000	0.2-1.6
LATVIA	96	4.8	310	1.55%	11-110	0.6-0.5
LITHUANIA	2010	7.0	440	1.59%	<10	<0.3
LUXEMBG	10	2.0	280	0.71%	0	0
MALTA	5	1.3	350	0.36%	0	0
NETHERL.	1063	10.8	310	2.04%	101-1000	0.6-6.0
POLAND	5300	14.4	220	6.32%	11-110	0.03-0.3
PORTUGAL	125	1.3	410	0.29%	<10	<0.1
ROMANIA	4090	18.9	250	8.18%	11-110	0.1-0.5
SLOVAKIA	2593	48.3	340	14.12%	0	0
SLOVENIA	120	6.0	250	2.29%	0	0
SPAIN	2808	10.9	380	1.58%	11-110	0-0.2
SWEDEN	55	0.6	390	0.15%	11-110	0.1-1.0
UK	2223	3.5	280	1.23%	11-110	0-0.2

‘Homeopathic prescribers’ equals the sum of homeopathic doctors plus homeopathic practitioners

Source: ECHAMP 2015, ECH 2012-2015, ECCH 2015, IVAA 2015, OECD 2012

Annex V: The implementation status of Article 16 (2) of Directive 2001/83/EC

EU Member States	16(2) not implemented	16(2) implemented including specific rules for proof of efficacy for homeopathic medicinal products	16(2) provided by national law but specific rules for proof of efficacy of homeopathic medicinal products are either not published or not in practice
AUSTRIA		•	
BELGIUM		•	
BULGARIA		•	
CROATIA	•		
CYPRUS	•		
CZECH REPUBLIC		•	
DENMARK			•
ESTONIA			• ⁹³
FINLAND		•	
FRANCE		•	
GERMANY		•	
GREECE			•
HUNGARY			•
IRELAND		•	
ITALY			•
LATVIA		•	
LITHUANIA		•	
LUXEMBOURG	•		
MALTA			•
NETHERLANDS			•
POLAND			•
PORTUGAL		•	
ROMANIA	•		
SLOVAK REPUBLIC			•
SLOVENIA	•		
SPAIN			•
SWEDEN	•		
UNITED KINGDOM		•	
Total	6	12	10

Source: ECHAMP 2015

⁹³ Submission of lower dilutions (<D4) is possible including Module 4

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.