
The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU



European Coalition on
Homeopathic and Anthroposophic Medicinal Products
European Economic Interest Group

ECHAMP's aim is to achieve full availability of homeopathic and anthroposophic medicinal products in the EU.

ECHAMP represents the industry for homeopathic and anthroposophic medicinal products in Europe. It endorses the important role that homeopathy and anthroposophic medicine play and can play in healthcare and seeks to maximise availability of homeopathic and anthroposophic medicinal products for all citizens of Europe. ECHAMP works to ensure an appropriate regulatory status for these safe, effective and high quality products.

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Executive Summary

This report seeks to measure the availability of the medicinal products for homeopathy and anthroposophic medicine, two traditional schools of medicine in the EU. Its aim is to generate objective and reliable information on the availability of these medicinal products in the EU for citizens or health care professionals. The key objectives of the report are to:

- collate data on EU-wide demand for and availability of homeopathic and anthroposophic medicinal products
- identify causes for lack of availability in the different Member States
- analyse the impact on availability of the status of implementation of EU pharmaceutical legislation for these products and the modalities of application of regulatory requirements at national level.

The report draws on a variety of sources – firstly pan-European socio-economic, sales and demand data relating to health care provision as regards services and products; secondly regulatory data collected by ECHAMP from referenced publications and the websites of the medicines agencies; and thirdly two independent surveys by PwC, the first on the regulatory status of homeopathic and anthroposophic products and the second testing the reality of their availability in a quantitative and a qualitative way at the point of delivery to the citizens.

Based on these data, modest to high demand for homeopathic and anthroposophic medicinal products is made visible in at least two thirds of the EU Member States, while – as demonstrated by the results of the Availability Survey – the widest direct availability of products in stock in pharmacy outlets was for those products requested by customers for self-medication. At the same time, there is a lack of comprehensive information on the regulatory status of the products in the Member States. The progress of enforcement of the relevant articles of Directive 2001/83/EC¹ is far from complete, and this both seriously limits present availability and raises a question mark over sustained future availability of the products as well.

The following four main deficits and needs are identified:

- i. The burden for the establishment and maintenance of registrations and marketing authorisations is disproportionate to the purpose of simplified registration and presents a permanent threat to the whole lifecycle of the thousands of homeopathic stocks which are needed by homeopathic prescribers. Mutual recognition/decentralised procedures require an effort that is also disproportionate to this area.
- ii. The assessment policy for applications for registrations according to Article 14 of the Directive is far from harmonised, increasing the administrative burden for applicants.
- iii. The lack of implementation and execution of adequate rules following Article 16.2 represents a threat to the clearly visible demand for OTC- and self-medication across the Member States. A more harmonised approach is also needed here.
- iv. Solutions for a specific approach should be found to meet the growing demand for anthroposophic medicinal products.

The report represents a significant benchmark for analysis of this sector of the pharmaceutical industry in the EU. It is hoped it will initiate a discussion on the further actions needed to overcome the deficits of the enforcement of the implementation of rules for these products in the EU Member States, and, where needed, the disproportionate requirements and high administrative burden of the Community legislation. This is needed to guarantee not just the quality and safety but also the availability of homeopathic and anthroposophic medicinal products and to ensure freedom of choice for the tens of thousands of prescribers and many millions of users in the EU.

¹ Articles 13 to 16.2 and Articles 68 and 69, European Commission Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

1. Introduction

1.1 Background to the report

Homeopathic and anthroposophic medicinal products (HAMPs) belong to the two traditional European medical approaches, homeopathy and anthroposophic medicine, each with their part to play in responsible and sustainable medication and self-medication. For the sake of public health, and given the shift of emphasis to patient-centredness and patient choice, these medicinal products should be fully available in the legal supply chain for the prescribers who choose to treat their patients in this way, and for the 100 million² citizens who, taking responsibility for their own health, choose these medicinal products for their own self-medication.

Doctors and practitioners rely on the availability of the medicinal products they prescribe. Patients and consumers demand the 'three As' - Availability, Accessibility and Affordability - of the medicinal products they have been prescribed or choose to use. However, associations of prescribers and patients report increasing lack of availability of HAMPs in the 27 Member States of the EU. This experience is reinforced by industry reports on the increasing restrictions in the range of HAMPs available in the legal supply chain, because of the bureaucratic regulatory burden and limitations and threats with respect to registration processes. Efficient homeopathic and anthroposophic medicine treatment is hindered by low or slow availability of HAMPs.

This report seeks to measure the availability of the medicinal products for these two traditional schools of medicine in the EU. Its aim is to generate objective and reliable information on the availability of HAMPs in the EU for the citizens or health care professionals who choose to use, recommend or prescribe these products.

This report is timed to feed into the Commission's current study of the availability of medicinal products for human use in the EU.³

1.2 Key questions

The basic question the report seeks to answer is whether or not homeopathic or anthroposophic medicinal products are available for citizens in the EU who ask for them at the normal point of delivery.

The report is based on the following understanding of 'availability' in the context of medicinal products: 'A medicinal product is available when it is functionally accessible and affordable to the patient or consumer who is asking for it in the outlet which is legally entitled to deliver such products. It should indeed be distributed along legally allowed, reliable and reachable channels, guaranteeing quality, safety and (for the products bearing indications) effectiveness of the products concerned.'

The key objectives of the report, in line with the Commission's own objectives, are to:

- collate data on the demand for HAMPs across the EU
- collate data on the availability of HAMPs across the EU
- identify causes for lack of availability in the different Member States
- analyse the impact on availability of the status of implementation of EU pharmaceutical legislation for HAMPs and the modalities of application of regulatory requirements at national level.

² Com (97) 362 Homeopathic Medicinal Products: Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74. Available from: www.echamp.eu/fileadmin/user_upload/Regulation/Commission_Report_Dir_92-73_and_92-74_Homeo_July_1997.pdf [quoted 05.04.12] ; Listed in OJ No C230/2 (29.07.97): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:1997:230:0002:0004:EN:PDF> [quoted 05.04.12]

³ N° EAHC/2011/Health/14 for the implementation of Framework Contract EAHC/2010/Health/01 Lot 1 Study on the availability of medicinal products for human use as listed on http://ec.europa.eu/eahc/health/sc_awarded_under_fw_c_2011.html and shown at http://ec.europa.eu/eahc/documents/health/tenders/2011/EN/EAHC_2011_14_Tender_Specification.pdf [quoted 12.04.12]

1.3 Structure of the report

This report draws on a variety of sources – firstly pan-European socio-economic, sales and demand data relating to health care provision as regards services and products; secondly regulatory data collected by ECHAMP from referenced publications, the websites of the medicines agencies, and a first independent survey by PwC;⁴ and thirdly the findings of a second independent survey by PwC⁵ to test the reality of the availability of HAMPs in a quantitative and a qualitative way at the point of delivery of medicinal products to the citizens. The report brings together and discusses the information generated throughout the different steps of the project.

Chapter 2 shows the outcome of the investigation of the socio-economic data of the sector, as regards both industry sales and the availability of health services by trained health care providers, the details of which are presented in a series of tables and charts in Annex I.

Chapter 3 presents the outcome of a threefold search for regulatory data, the sources for which are included in Annex II. Annex II.1 provides a synthesis of the findings of the three different sources: firstly the independent survey of the medicines agencies ('Regulatory Status Survey', PwC, December 2010) (Annex II.2); secondly a website search of the 27 national medicines agencies (December 2010) and thirdly a follow up website search in December 2011 (Annex II.3).

Chapter 4 presents the results of the second independent survey by PwC, this one on the availability of HAMPs ('Availability Survey', April 2012). The full survey results are available in Annex III, as is an explanation of the process for the selection of countries and products included in the survey.

Chapter 5 brings together the different elements in a discussion that considers a range of issues affecting the availability of homeopathic and anthroposophic medicinal products and addresses a number of major concerns relating to non-availability.

The report finishes with an analysis of the deficits of the implementation of rules for homeopathic medicinal products in the EU and their enforcement in the Member States. It provides an urgent recommendation to discuss the situation in the frame of future initiatives to solve the problems.

1.4 Importance and limitations of the report

This report brings together the results of a series of initiatives over a period of about two years. For a first such comprehensive exercise, it was perhaps inevitable that we would encounter a number of difficulties, especially as regards the availability of reliable data.

Most of the data are not publicly available; they are also piecemeal and incomplete. The base data come from industry, other stakeholders, and research on the websites of the medicines agencies. To provide as complete a picture as possible, ECHAMP commissioned PwC to carry out the two independent surveys – the Regulatory Status Survey and the Availability Survey. However, the responses from the national medicines agencies to the Regulatory Status Survey were also incomplete – with only fifteen completed responses to the 27 questionnaires that were sent out. Due to this unsatisfactory result, the data was made more complete with intensive research on the medicines agencies' websites.

The selection of five countries and six products for the Availability Survey was made with care,⁶ and both the selected countries and the selected products were defined to be as representative as possible of the daily

⁴ Annex II.2 Survey on Homeopathic and Anthroposophic Medicinal Products - Regulatory Status Survey Report, PwC, December 2010

⁵ Annex III.2: Survey on the Availability of Homeopathic and Anthroposophic Medicinal Products in five Member States of the EU, PwC, April 2012

⁶ See Annex III.1 Background to the Survey

experience of citizens and prescribers as regards the availability of the medicinal products they choose or prescribe.

In its entirety, the report contains all the information available, including the outcome of two independent surveys, and represents a significant benchmark for analysis of this sector of the pharmaceutical sector in the EU.

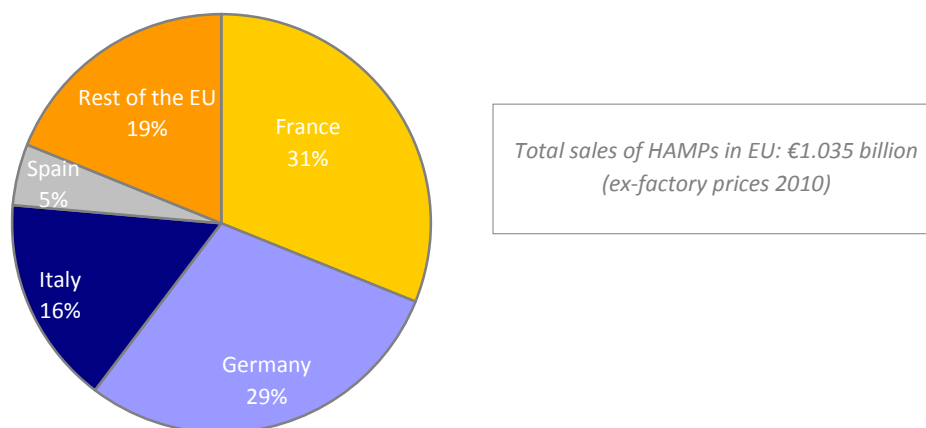
2. Socio-Economic, Demand and Sales Data

The availability of medicines is dictated by supply, industrial interests and demand. Factors influencing demand include levels of use of medicinal products, numbers of health care providers, numbers of medicines prescribers and overall expenditure on medicines, as well as more wide-ranging factors such as market structure and regulatory policies. Variations in these factors may mean variations between the Member States in the availability of medicines.

This chapter presents figures which describe the general economic and social picture in all Member States, including data regarding the various markets for homeopathic and anthroposophic medicinal products (HAMPs). It also presents the relation to Gross Domestic Product (GDP), population size and to relative purchasing power. The source data for the results presented in the text below are provided in Annex I of this report. They include: data on the sales of HAMPs related to population and prescribers (Annex I Figure 1); the basic data on prescribers of HAMPs (Annex I Figure 2); the absolute sales data of the pharmaceutical industry in general and specifically the industry for HAMPs (Annex I Figure 3); and the socio-economic background data (Annex I Figure 4). To make this data more accessible, Annex I also includes additional charts, some of which are reproduced below and others of which are referred to in the following text.

2.1 The markets for homeopathic and anthroposophic medicinal products

Figure 2.1: Sales of HAMPs: Market share of the largest EU markets (2010)



Source: ECHAMP (Annex I Figure 3 (i); also Annex I Figures 5 and 6)

Figure 2.1 shows that approximately 80% of the EU market for HAMPs is held by the three largest markets - France, Germany, and Italy. Together they represent 40% of the EU population. This represents total sales of HAMPs of about €320 million⁷ in France, €300 million in Germany, and nearly €170 million in Italy. There is a big discrepancy between the size of these markets and the size of all the other markets in the EU: for Austria, Belgium, the Netherlands, Poland, Spain and the United Kingdom, the sales figures range between €20 and €50 million, and in all other Member States, they are well under €10 million.⁸ In total, HAMPs represent 0.73% of the entire pharma market of the EU.⁹

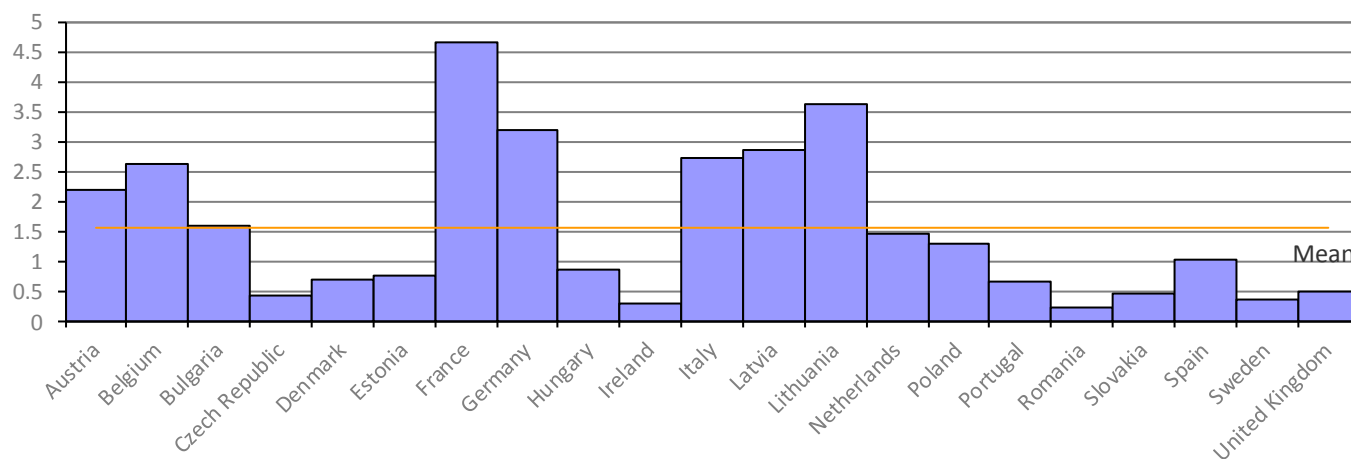
⁷ Sales of HAMPs in 2010 (ex-factory prices)

⁸ Annex I Figure 6

⁹ Annex I Figure 7

However, the wide differences in sales figures of HAMPs between the groups of Member States listed above do not represent a realistic picture with respect to the demand for HAMPs: firstly, France, Germany and Italy also represent the largest markets with respect to total pharma sales.¹⁰ In addition, consideration of population size and relative purchasing power might lead to a more balanced picture of the EU. Therefore, in order to approach a closer description in terms of demand and availability, the sales data of HAMPs per Member State are adjusted to the size of population and GDP per capita in Purchasing Power Standards (PPS) (Figure 2.2 below).

Figure 2.2: Sales of homeopathic and anthroposophic medicinal products per inhabitant in relation to GDP per capita expressed in PPS (€)



Source: Annex I Figure 1 (ii); see also Annex I Figure 8

The European mean of adjusted sales¹¹ is €1.54. Comparison of the individual Member State figures with this mean value provides the following picture:

2.1.1 Member States with adjusted sales around the European average

BULGARIA, NETHERLANDS, POLAND, SPAIN

The adjusted sales figures of HAMPs in Bulgaria, Netherlands, Poland and Spain approximately reflect the European average with values of €1.58, €1.47, €1.3 and albeit somewhat lower, €1.01 per inhabitant respectively. These sales can be understood as an expression of a certain demand by the population which is matched by a certain availability of HAMPs.

The sales or, in other words, this demand, might be driven by different forces. In order to approximate a certain descriptive comparison of the forces driving demand, this report also presents the number of prescribers¹² specifically trained in homeopathy (homeopathic prescribers) per 100,000 inhabitants.¹³ Poland, Spain and Netherlands have 14.4, 10.9 and 10.8 homeopathic prescribers per 100,000 inhabitants respectively and these numbers are very close to the European mean of 11.4. In contrast, Bulgaria shows a very different profile with 21.6 prescribers per 100,000 inhabitants. In Poland, Spain and Bulgaria, the number of anthroposophic doctors

¹⁰ Annex I Figure 3 (iii)

¹¹ For 21 Member States

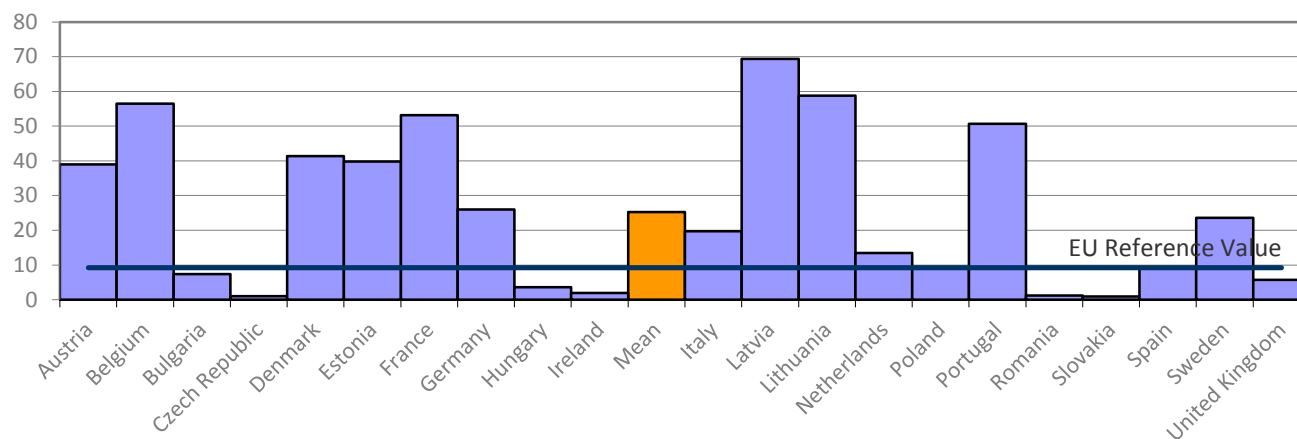
¹² Depending on the different legal situations in the countries, homeopathic prescribers may be doctors and/or practitioners trained in homeopathy (Annex I Figure 2 (ii) and (iv)); total homeopathic prescribers equals the sum of homeopathic doctors plus homeopathic practitioners (Annex I Figure 2 (vi))

¹³ Annex I Figure 9

per 100,000 inhabitants is marginal.¹⁴ Only in Netherlands should a considerable number of anthroposophic doctors not be excluded, although precise data are not given.

In order to allow a rough comparison between the Member States as regards the proportion of demand driven by prescribers, versus the demand driven by OTC-based medication or self-medication, the relationship between sales and homeopathic prescribers is calculated (Figure 2.3 below).

Figure 2.3: Sales of homeopathic and anthroposophic medicinal products per homeopathic prescriber in relation to GDP per capita expressed in PPS (€000)



Source: Annex I Figure 1 (iv); see also Annex I Figure 10

In view of the heterogeneity of the data, **an EU reference situation** is defined (Figure 2.4) for this report, **at a value of around €9,200 per prescriber**, as found exactly in Spain and nearly in Poland. This is used as a reference for comparison regarding the relationship of demand driven by prescribers versus that driven by OTC based medication and self-medication.

In contrast to this, the figure for Bulgaria, where there is a higher number of homeopathic prescribers, is slightly lower at €7,400 per prescriber. Bearing in mind that direct correlations do not exist between sales and prescribers across the different EU Member States (Figure 2.4), the figures nevertheless indicate that the proportion of sales of HAMPs in relation to homeopathic prescribers can be considered higher in Poland, Spain and potentially in Netherlands than in Bulgaria.

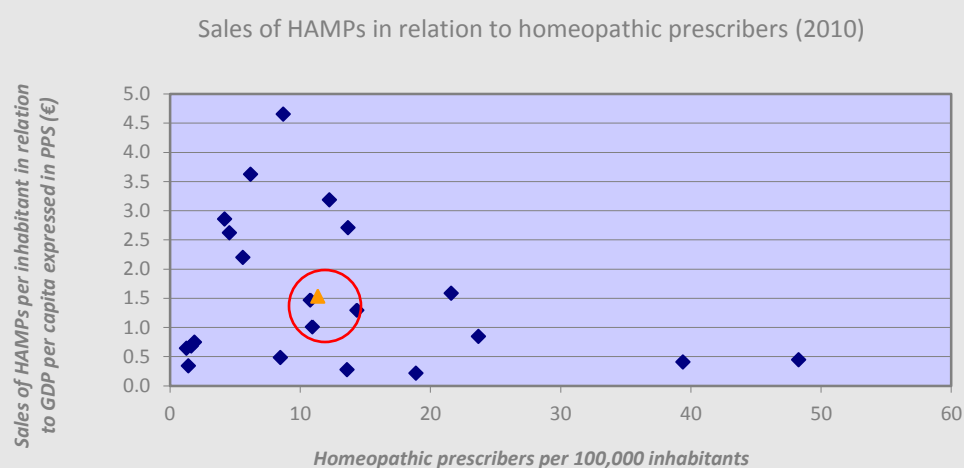
¹⁴ Annex I Figure 2 (viii)

Figure 2.4 European reference situation

The average European sales per prescriber are €25,300 (Figure 2.3). However, it is not clear how far the prescribers directly contribute to sales figures. And, as the table below shows, the data do not provide any hint for a direct correlation between level of sales and number of prescribers in a country. Moreover, there are Member States where:

- i. low sales are matched by high numbers of homeopathic prescribers
- ii. low sales meet low numbers of prescribers at the same time
- iii. high sales meet low numbers of prescribers, and
- iv. all possible combinations around the average sales or average number of prescribers.

The combination of high sales and high number of prescribers does not exist.



Source: Annex I Figure 1(ii) and Figure 9

However, a descriptive comparison of the situations in the Member States might be helpful. In view of this heterogeneity, the alternative approach is chosen to define an **EU reference situation** as a base for comparison of the individual Member States; that is to define the situation of those countries where both the average sales of HAMPs (adjusted by population and relative purchasing power) and the average number of prescribers per 100,000 inhabitants are found at the same time. This ‘double’ average situation is found in Poland, Netherlands and Spain. As described above, the adjusted sales per inhabitant of these three countries rank around the average, and at the same time the numbers of homeopathic prescribers per 100,000 inhabitants are similar to the European mean.

From this, Netherlands, Spain and Poland could be defined as the EU reference situation. The values are €13,500, €9,200 and €9,100. However, the value for Netherlands may still represent an overestimation, if we take account of the vague values of anthroposophic doctors in this country. Therefore, for this report, the value of around €9,200 per prescriber is defined as the EU reference situation (Figure 2.3).

2.1.2 Member States with relatively high adjusted sales (clearly above the European average)

AUSTRIA, BELGIUM, FRANCE, GERMANY, ITALY, LATVIA, LITHUANIA

There are seven Member States, for which the adjusted sales are clearly higher than the European average. These countries (and their sales per inhabitant) are: France (€4.65), Lithuania (€3.62), Germany (€3.18), Latvia (€2.86), Italy (€2.71), Belgium (€2.62) and Austria (€2.2) (Figure 2.2). The interpretation of these sales figures shows that in these countries, a clearly visible demand for HAMPs is matched with corresponding availability.

This visible demand is also reflected by a ratio of sales of HAMPs to the total pharma market that is above the European average.¹⁵ The European mean value is 0.73 %, and sales of HAMPs represent 1.33% of the total pharma market in Latvia, 1.22% in France, 1.13% in Germany, 1.11 % in Lithuania, 0.92 % in Italy, 0.87 % in Belgium and 0.74 % in Austria.

In these countries, while significantly fewer than the European average of 11.4 homeopathic prescribers per 100,000 inhabitants are found in Belgium (4.8) Latvia (4.2), Austria (5.6) and Lithuania (6.2), the figures of France (8.7), Germany (12.3) and Italy (13.6) are closer to the EU mean value.¹⁶

Again, the ratio of sales per prescriber (Figure 2.3) differs between these countries: with (in €000) 69.4 in Latvia, 58.8 in Lithuania, 56.5 in Belgium, 53.0 in France, 39.0 in Austria, 26.0 in Germany and 19.7 in Italy, the figures are clearly considerably higher than the value of 9.2 defined as the EU reference situation (see Figure 2.4). This relationship may indicate a considerable difference with respect to prescriber independent demand for HAMPs in these seven countries.

In so far as figures regarding anthroposophic doctors per inhabitant¹⁷ are available, they do not inverse this trend: the available data are rather imprecise. The figures which may be relevant to a certain extent are those indicated for Germany.

2.1.3 Member States with relatively low adjusted sales (clearly below the European average)

CZECH REPUBLIC, DENMARK, ESTONIA, HUNGARY, IRELAND, PORTUGAL, ROMANIA, SLOVAKIA,
SWEDEN, UNITED KINGDOM

The adjusted sales of HAMPs per inhabitant (Figure 2.2) are significantly below the EU mean value of €1.54 in Hungary (0.84), Estonia (0.74), Denmark (0.68), Portugal (0.64), United Kingdom (0.48), Slovakia (0.44), Czech Republic (0.41), Sweden (0.34), Ireland (0.27) and Romania (0.21). These relatively low sales correlate with a ratio of sales of HAMPs to the total pharma market that is much below the EU average.¹⁸ While the EU mean value of sales of HAMPs represents 0.73 % of the total pharma market, the ratios in these ten countries range between 0.08 % and 0.33 %. So in these ten Member States, no clear demand and/or no clear availability of HAMPs can be demonstrated via figures represented by sales of HAMPs.

Other possible clues of a demand for HAMPs might be indicated by the number of homeopathic prescribers. Estonia, Portugal, Sweden and Denmark are four countries out of these ten Member States, where the figures of homeopathic prescribers are quite marginal with 1.9 to 1.3 prescribers per 100,000 inhabitants.¹⁹ The figures for anthroposophic doctors per 100,000 inhabitants are comparable in their order of magnitude.²⁰

However, a completely controversial picture is found in Slovakia, the Czech Republic, Hungary and Romania, with 48.3, 39.4, 23.7 and 18.9 homeopathic prescribers per 100,000 inhabitants respectively. The figures for these four Member States greatly exceed the European average of 11.4 homeopathic prescribers per 100,000 inhabitants. A medium range of prescribers is found in Ireland or the United Kingdom with 13.6 and 8.5 homeopathic prescribers per 100,000 inhabitants respectively. These prescriber figures clearly indicate a demand for homeopathic medicinal products. (In contrast to homeopathic prescribers, numbers of anthroposophic doctors in these countries are marginal.)

¹⁵ Annex I Figure 7

¹⁶ Annex I Figure 9

¹⁷ Annex I Figure 2 (viii)

¹⁸ Annex I Figure 7

¹⁹ Annex I Figure 9

²⁰ With the exception of Estonia: Here the available data (indicating a range) are too imprecise to allow a statement; relevant numbers of prescribers cannot be excluded.

In addition, the figures showing the ratio of sales of HAMPs to homeopathic prescribers (Figure 2.3) show a range between €900 and €5,700 for these six Member States (Slovakia, Czech Republic, Hungary and Romania, United Kingdom and Ireland). There is a noticeable discrepancy between these countries and the countries of the group of Member States with relatively high sales (Section 2.1.2), which means that the relative proportion of sales driven by OTC or self-medication may be clearly lower than the EU reference situation and much lower than in the countries with high sales.

2.1.4 Member States without sales figures

CYPRUS, FINLAND, GREECE, LUXEMBOURG, MALTA, SLOVENIA

No sales figures for HAMPs are available from the following six Member States: Cyprus, Finland, Greece, Luxembourg, Malta and Slovenia.²¹ For all countries except Luxembourg, the numbers of homeopathic prescribers describe a certain, rather small demand for HAMPs.²² The range of prescribers per 100,000 inhabitants is from 2.6 in Greece, to 2.7 in Cyprus, 3.0 in Malta 6.0 in Slovenia and 9.3 in Finland. In addition, in Finland, a small but relevant number of anthroposophic doctors of 0.2-1.9 per 100,000 inhabitants can be found.²³

2.2 Summary

Approximately 80% of the EU market for HAMPs is held by the three largest markets - France, Germany, and Italy (together representing 40% of the EU population).

In addition, an analysis of the figures reflecting the demand of the population, that is sales figures adjusted to the size of population and the relative purchasing power, indicates a strong demand in Belgium, Latvia, Lithuania and Austria in addition to France, Germany and Italy. In each of these seven countries, the ratio of sales of HAMPs compared to the total pharma market exceeds the European average.

At the same time, the number of prescribers per inhabitant represents an alternative indicator of demand for HAMPs. In this category, the highest figures are found in Czech Republic, Slovakia, Hungary, Bulgaria, Romania and Poland. While Bulgaria and Poland range in the group of Member States around the EU average of sales adjusted to size of population and relative purchasing power, the other four Member States fall into the category of those Member States with relatively low adjusted sales. While in Ireland and the UK the adjusted sales are comparably low, at least a figure of homeopathic prescribers ranging around the EU average is found.

In contrast to this, only marginal demand can be made visible by our figures in Estonia, Denmark, Sweden and Portugal as expressed in terms of sales or prescribers. No sales figures are available for Cyprus, Finland, Greece, Luxembourg, Malta or Slovenia, and in all these countries except Luxembourg, the demand expressed in terms of prescribers is similarly small.

An analysis of sales per prescriber (adjusted to relative purchasing power) provides the picture that the proportion of sales in relation to the number of prescribers is highest in Latvia, Lithuania, Belgium and France, followed by Germany and Italy (in other words these are likely to have good OTC sales). The situation defined arbitrarily as the EU reference situation (average of adjusted sales matched by average number of prescribers per inhabitant) is found in Spain and Poland. The figures for Netherlands (slightly higher) and Bulgaria (slightly lower) closely group around this reference, while the figures of Czech Republic, Slovakia, Hungary and Romania range significantly below.

²¹ Annex I Figure 3 (i)

²² Annex I Figure 9

²³ Annex I Figure 2 (viii)

3. The Regulatory Status of Homeopathic and Anthroposophic Medicinal Products in Europe

3.1 The legal status

The authorisation 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 status of implementation of this legal basis varies considerably in the 27 Member States of the EU.²⁴ Since the implementation of Article 14 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 27 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.

Article 16.2 (marketing authorisation), however, for which the implementation is optional but must be completed with the publication of specific national rules for pre-clinical tests and clinical trials, has been fully implemented in only fourteen Member States. There are four Member States in which Article 16.2 has not been implemented; in these countries Article 16.1 (full marketing authorisation in accordance with Articles 8, 10, 10a, b, c and 11) applies. In the remaining nine Member States, the optional implementation of Article 16.2 is provided for, so Article 16.1 does not apply; however, the specific rules still remain to be published.

In addition, a number of countries apply the provision of Article 13, which allows Member States to keep on the national market homeopathic medicinal products which are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. These products are known as 'grandfathered products'.

3.2 Sources of data on the regulatory situation of homeopathic and anthroposophic medicinal products

Annex II.1 presents a synthesis of data on the regulatory situation of homeopathic and anthroposophic medicinal products (HAMPs) that has been collated from three main sources:

- the results of an independent survey by (PwC, December 2010)²⁵ on the regulatory status of homeopathic and anthroposophic medicinal products in the EU (Regulatory Status Survey), based on a questionnaire sent to the 27 national medicines agencies; fifteen agencies submitted the completed questionnaire and this produced certain data on the number of notifications, registrations, mutual recognition procedures and marketing authorisations of HAMPs in the different EU Member States (Annex II.2)
- information from the websites of the medicines agencies of the 27 Member States²⁶ as at December 2010
- a further investigation of the websites of the 27 national medicines agencies²⁷ (ECHAMP, December 2011) in order to complete as full as possible an overview of the situation at the end of 2011 (Annex II.3).

²⁴ Annex II..1.i

²⁵ Annex II.2 Survey on Homeopathic and Anthroposophic Medicinal Products - Regulatory Status Survey Report, PwC, December 2010

²⁶ Annex II.2 Regulatory Status Survey, Annex C

²⁷ Annex II.3 Medicines Agencies' Sites with Information on Registration of Homeopathic and Anthroposophic Medicinal Products, ECHAMP, December 2011

The two website searches complemented the results of the Regulatory Status Survey with information (figures or lists according to the different agencies) on Austria, France, Germany, Hungary, the Netherlands, Poland, Portugal and Slovakia. In some instances where none of the sources revealed data, the information has been supplemented by industry knowledge.

3.3 Data from the threefold investigation

Despite this threefold investigation, the picture is still incomplete. A number of national agencies do not make the figures public.

3.3.1 Notifications

The Regulatory Status Survey revealed an estimated number of homeopathic products on the market in some Member States as well as the number of products notified in these countries in the 1990s (Annex II.1.ii and II.1.iii). The survey showed that in a number of countries, namely Belgium, Denmark, Italy, Portugal and Sweden, applicants were invited to notify the products they wanted to register or have authorised. ECHAMP's own experience is that notifications were also collected in the Netherlands and Spain in 1995.

3.3.2 Article 14 registrations

As regards the number of Article 14 registrations (Annex II.1.iv), the Regulatory Status Survey contains figures given by the medicines agencies in ten Member States (Annex II.1.iv (a)). In addition, the two web searches revealed further data in December 2010 (Annex II.1.iv (b)) and December 2011 (Annex II.1.iv (c)), sometimes in the form of statistics, sometimes as a complete list of finished homeopathic medicinal products. These website searches provide information on registrations or on-going evaluation of submitted applications in fifteen Member States. In total, the three sources provided data for seventeen countries, leaving ten countries for which there was no data. Furthermore there were some considerable inconsistencies between the different sources (for instance in Denmark, Finland, Portugal and the United Kingdom).

The number of registrations or applications in evaluation appears comparably negligible in Belgium, Denmark, Finland, Ireland and Romania, while the figures in some Member States such as Austria, Czech Republic, France, Germany, Hungary, the Netherlands, Slovakia, Sweden and especially Portugal are comparably high. The high figure from Portugal can be explained by the fact that the product list found on the web page contains all the finished products declared by the applicants while the survey questionnaire asked only for the number of homeopathic stocks that have been registered. None of the data collection sources provided any figures regarding submissions or registrations from Bulgaria, Estonia, Greece, Italy, Latvia, Lithuania, Luxembourg, Malta, Slovenia or Spain. Industry experience confirms that there were no registrations in Spain or Italy at the dates of the website searches.

3.3.3 Mutual recognition procedure

There is very little experience with the mutual recognition procedure for registered homeopathic medicinal products (see Annex II.1.v). Although the data collected in the Regulatory Status Survey in 2010 refers to at least three procedures (Netherlands), this contradicts industry knowledge. According to ECHAMP members, there is only one mutual recognition procedure that has been finalised (in accordance with Article 29.2) and this in three Member States, one Reference Member State and two Concerned Member States. A second procedure, this one in accordance with Article 29.3 (decentralised procedure) has been finalised with the participation of five Member States, one Reference Member State and four Concerned Member States.

3.3.4 Article 16.2 marketing authorisations

Annex II.1.i (b) shows the status of the optional implementation of Article 16.2 (full implementation, partial implementation or non-implementation) in the 27 Member States. As regards Article 16.2 marketing authorisations (Annex II.1.vi) in the fourteen Member States where specific rules are available or foreseen, there

was no consistency between the figures declared by the agencies in the Regulatory Status Survey in 2010 (Annex II.1.vi (a)) and the information on the agencies' websites in December 2010 (Annex II.1.vi (b)) or December 2011 (Annex II.1.vi (c)). The available data show a picture with rather heterogeneous numbers of marketing authorisations: Austria (797), Belgium (1), Bulgaria (74), Estonia (22) France (34), Germany (1270), Netherlands (619) and the United Kingdom (1). The data collection provided no data from the following Member States where article 16.2 has been implemented: Ireland, Latvia, Lithuania, Poland and Spain. No authorisations exist in Portugal.

3.4 Anthroposophic medicinal products

The EU regulatory picture for anthroposophic medicinal products (AMPs) is a fragmented one, and anthroposophic medicinal products are not yet part of the legislation in place in the European Union, nor in most of the Member States. Homeopathic medicinal products have a legal basis in Directive 2001/83/EC, as detailed above, and Article 1.5 of the Directive, as enlarged by 'Recital 22', defines that this applies equally to all AMPs that are homeopathically manufactured. Traditional herbal medicinal products are defined in Article 1.29 and Article 16a (1) of the Directive.²⁸ A number of limitations exclude the large majority of anthroposophic medicinal products from this simplified so-called 'herbal traditional use registration.'

The figures in the full Regulatory Status Survey (Annex II.2) show the presence of anthroposophic medicinal products on the market in Germany, Belgium (1360), Finland (109), Portugal (2) and the United Kingdom (362). German drug law contains a definition of anthroposophic medicinal products in Article 4.33, referring to the special anthroposophic manufacturing procedures and the principles of anthroposophic medicine. In Germany, the medicines agency publishes detailed and regularly updated statistics on its website specified per category, including anthroposophic medicinal products (1041 in February 2012).

The Regulatory Status Survey also indicates that anthroposophic medicinal products have a full legal status in Switzerland and that about 2200 anthroposophic medicinal products are on the market in this country. In its detailed answer, the Swiss agency referred to the different regulatory procedures for anthroposophic medicinal products in Switzerland. 680 anthroposophic medicinal products have been granted a marketing authorisation, the other ones are registered, notified (a procedure foreseen in Swiss medicines law) or still in the application procedure.

²⁸ Article 1.29: Traditional herbal medicinal product: a herbal medicinal product that fulfils the conditions laid down in Article 16a(1); Article 16a(1): A simplified registration procedure (hereinafter 'traditional-use registration') is hereby established for herbal medicinal products which fulfil all of the following criteria:

- (a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
- (b) they are exclusively for administration in accordance with a specified strength and posology;
- (c) they are an oral, external and/or inhalation preparation;
- (d) the period of traditional use as laid down in Article 16c(1)(c) has elapsed;
- (e) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

4. Survey on the Availability of Homeopathic and Anthroposophic Medicinal Products

An independent survey on the availability of homeopathic and anthroposophic medicinal products (HAMPs) was commissioned from PwC.²⁹ This was executed for six products in five Member States between January and March 2012. PwC summarises the results as follows:

“Based on the countries surveyed and the homeopathic and anthroposophic medicinal products questioned, a difference in the availability of HAMPs is noticeable:

- Some countries have a better developed market of HAMPs, such as France, Spain and especially Germany showing highest availability of most products and short delivery times if a product order has been placed.
- Specific brands of medicinal products with no therapeutic indication, reflecting the classical single remedy homeopathy, are often difficult to find immediately (i.e. without ordering). However, these products can mostly be delivered to customers after a product order has been placed. Of the two products questioned in the survey within this segment, Formica (rufa) was the hardest one to find.
- However, requesting homeopathic medicinal products for specific symptoms, i.e. medicinal products with a therapeutic indication (instead of specific brands for these symptoms), results in much better direct availabilities. Self-medication seems to be well-developed for the indications surveyed.
- Anthroposophic medicinal products are seldom directly available in the countries surveyed. Only in countries with a more or less well-functioning HAMP regulatory system, the products surveyed can be ordered and delivered accordingly, with Germany as best-in-class.
- The products’ availability does not show significant differences across the geographical regions within the countries surveyed: the availability of the products questioned is more or less the same in big cities, middle-sized cities, and countryside areas.
- As regards registration or authorisation numbers, a validation of the products provided has been done by a qualified person and led to the following general statements:
 - In Spain none of the products provided carried an authorisation number.
 - In France most of the products did not show an authorisation number either.
 - In Germany and Bulgaria most of the products provided carried an authorisation number.
 - In Romania the situation could not be validated due to the loss of the pack with the samples in the post.”

²⁹ Annex III.2: Survey on the Availability of Homeopathic and Anthroposophic Products in five Member States of the EU, PwC, April 2012

5. Discussion

To date, there exists no comprehensive information on the situation of homeopathic and anthroposophic medicinal products (HAMPs) in the EU. A European Commission report in 1997³⁰ dealt with the implementation of Directive 92/73/EEC in the EU 15 (before 2004) from a legal and regulatory point of view. In addition, a 2008 Commission Report on the implementation of Directive 2004/24/EC (specific provisions applicable to traditional herbal medicinal products)³¹ paid special attention to the situation of anthroposophic medicinal products.

This report provides for the first time comprehensive and recent information on the demand for HAMPs in the EU as well as on their regulatory status and availability.

5.1 The demand for homeopathic and anthroposophic medicinal products in the EU

The results of the report demonstrate that a demand for homeopathic medicinal products is visible in most EU Member States, either in the form of sales data, or in the form of numbers of prescribers, or as demonstrated by direct availability of products in pharmacies driven by the everyday demand of pharmacy customers.

The absolute sales of HAMPs vary between the Member States by a factor of up to 1000, and are dominated by the three large countries, France, Germany and Italy. However, an analysis of sales data of HAMPs and data on the number of homeopathic prescribers in relation to population size and relative purchasing power gives an indication of the demand for HAMPs from different angles. The results clearly contradict the broadly held opinion that tradition of and demand for HAMPs is limited to France, Germany and Italy only.

The factors driving this demand vary considerably between the Member States. There are countries with a high predominance of homeopathic prescribers in relation to sales (compared to the EU average), such as Czech Republic, Slovakia, Hungary and Romania. On the other hand, there are countries like Latvia, Lithuania, Belgium and France, where sales data are high compared to the numbers of homeopathic prescribers.

In addition, a significant result of the Availability Survey can be emphasised: almost all pharmacies, in all five countries examined, were able to provide homeopathic medicinal products for the specific therapeutic needs of a common cold (or 'flu or 'flu-like symptoms), or stress (or exhaustion) as requested by the data collectors. In a few cases, where a speciality product with an indication was not available, the pharmacist proposed a single remedy or Schüssler Salts, based on his/her knowledge of self-medication with homeopathy. This means that the products were directly available in the pharmacy outlets, that the pharmacists are used to meeting this demand, and thus that the demand clearly exists. The consistency of this result is remarkable, as the products were available, independently both of the legal or regulatory situation for homeopathic medicinal products with indications in the country and of the demand profile of the Member State.

Furthermore, the fact that the data do not demonstrate relevant demand in certain Member States may not preclude the existence of a demand for or interest in HAMPs in these countries. It may simply mean that for some countries, we were unable to collect reliable data to make visible this demand. For example, in this context, the comparatively high number of registrations in Portugal and Sweden needs to be further analysed.

³⁰ Com (97) 362 Homeopathic Medicinal Products: Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74. Available from: www.echamp.eu/fileadmin/user_upload/Regulation/Commission_Report_Dir_92-73_and_92-74_Homeo_July_1997.pdf [quoted 05.04.12] ; the report is listed in OJ No C 230/2 dated 29.07.97:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:1997:230:0002:0004:EN:PDF> [quoted 05.04.12]

³¹ Com (2008) 584 Communication from the Commission to the Council and the European Parliament concerning the report on the experience acquired as a result of the application of the provision of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0584:FIN:en:PDF> [quoted 05.04.12]

Homeopathy originated in Germany and France and quickly spread across Europe and around the world.³² The facts of the report confirm the recent findings of historians, i.e. that political, social or cultural conditions may have hidden the visibility of these traditions for a certain period of time, but that the roots continued to exist.³³ As the data underline, as soon as the conditions allowed, the demand became clearly visible. EU-wide demand was also confirmed in the 1997 Commission Report by means of three relevant figures showing the citizens' demand, the sales and for some countries the volumes: **Three Europeans out of four** know about homeopathy and **29%** use it for their health care. Homeopathic medicinal products today account for a little **over 1%** of the gross sales of the European pharmaceutical industry. In France, Germany and the Netherlands this figure is over 2% in value and 5% by volume.³⁴ Updated figures, including the history of market development in all EU Member States, can be found in the ECHAMP Facts and Figures second and third editions (2007 and 2011).³⁵

Anthroposophic medicine finds increasing recognition both among the general public and the academic world.³⁶

5.2 The regulatory status of HAMPs in the EU

The results of this report demonstrate the difficulty of collecting reliable data on the regulatory status of HAMPs in the EU. A limited number of medicines agencies responded and validated the answer to the Regulatory Status Survey questionnaire in 2010. In addition, a limited number of agencies provide public data about the numbers of notifications, registrations and marketing authorisations in the EU. In some cases, the information on the web pages changed significantly between December 2010 and December 2011. In so far as figures are available from the agencies' websites, their presentation and the figures themselves are in many cases not comparable. In some cases, there were also inconsistencies between the results of the Regulatory Status Survey and the results of the website searches.

One reason for this is that registrations may cover a series of potencies,³⁷ and the numbers of registrations do not necessarily provide information about the number of finished products. This is in line with the concept of the therapy. Different figures reflect the heterogeneity of understanding regarding the wish to present figures of finished products or not, and with respect to the definition of an application by a Member State. In some Member States, an application represents all dosage forms and a series of potencies of a certain stock, whilst in others, it is only one series of potencies of one dosage form of a stock.

For some Member States, despite the fact that the data on sales or prescribers show considerable demand and/or availability, it was not possible to gather figures with respect to the regulatory status. Nevertheless it is known, for example, that in Latvia and Lithuania, official and also recent industrial registrations do exist according to Article 14, as do marketing authorisations according to Article 16.2. In addition, it is to be stated that the availability of HAMPs in Spain is based on transition rules and notifications.

As shown in Chapter 3, the degree of implementation of Directive 2001/83/EC varies considerably between Member States. Although the available data on the regulatory status do not allow a complete quantitative statement, the following statements give an indication as to the slow progress in the field of registrations and authorisations for homeopathic medicinal products in the European Union:

³² Martin Dinges (Editor): *Weltgeschichte der Homöopathie*. München: C.H. Beck; 1996

³³ Robert Jütte: *The hidden roots: A history of Homeopathy in Northern, Central and Eastern Europe* [Internet]. Stuttgart: Institute for the History of Medicine of the Robert Bosch Foundation; 2006. Martin Schmidt (Editor): *Strömungen der Homöopathie: Konzepte – Lehrer – Verbreitung*. Essen; KVC-Verlag; 2000; available from: [http://www.igm-bosch.de/content/language2/downloads/Hidden_Roots\(1\).pdf](http://www.igm-bosch.de/content/language2/downloads/Hidden_Roots(1).pdf) [quoted 11.04.12]

³⁴ Com (97) 362 Homeopathic Medicinal Products: Commission Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74; available from: www.echamp.eu/fileadmin/user_upload/Regulation/Commission_Report_Dir_92-73_and_92-74_Homeo_July_1997.pdf [quoted 05.04.12]; The report is listed in OJ No C 230/2 dated 29.07.97 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:1997:230:0002:0004:EN:PDF> [quoted 05.04.12]

³⁵ ECHAMP: *Homeopathic and Anthroposophic Medicinal Products in the European Union: Facts and Figures 2011*. 3rd Edition. Brussels, 2011; available from: <http://www.echamp.eu/publications/brochures.html> [quoted 11.04.12]

³⁶ www.iva.eu/?p=20 [quoted 12.04.12]

³⁷ Article 15 of Directive 2001/83/EC: 'An application for special, simplified registration may cover a series of medicinal products derived from the same homeopathic stock or stocks.'

- i. In some Member States, there are notifications without substantial figures of final registrations (for example Belgium, Italy and Spain)
- ii. In some Member States, major efforts are still required to transfer submitted dossiers into final registrations (for example France, Poland and Portugal)
- iii. In some Member States, where there are no known notifications, the number of final registrations is negligible compared to the expressed need for 3,000 stocks normally required by a homeopathic prescriber³⁸ (for example Finland and Ireland).
- iv. There is a substantial discrepancy between the number of Member States which have legally implemented Article 16.2 (14) and the number which have actually granted marketing authorisations according to Article 16.2 (for example Belgium, Finland, Ireland, Portugal, Spain and United Kingdom)
- v. As at April 2012, only one Mutual Recognition procedure and one Decentralised Procedure (the option for which was first introduced in 2004) have been initiated and completed to date.

The presence of anthroposophic medicinal products on the market in the EU Member States, and their national authorisation or registration are related to national policy that was already in place before the publication of the specific homeopathic Directive in 1992, for example in Germany, United Kingdom, Finland and Sweden. In Belgium, homeopathically-prepared anthroposophic medicinal products have been the subject of a notification procedure together with the homeopathic medicinal products. The overall picture of the regulatory status of anthroposophic medicinal products in the EU is very fragmented.

5.3 The availability of HAMPs in the EU

Information about the availability of HAMPs in this report comes from two sources: firstly, indirect information provided by sales data and secondly the Availability Survey. In countries characterised by considerable sales, a clear availability of HAMPs can be deduced (see 5.1). On the other hand, in countries with low sales data, the availability of products is not directly obvious.

The Availability Survey was executed for six products in five Member States. The intention was to demonstrate the availability of HAMPs for different regulatory situations and by this to complement both the data on regulatory status and the socio-economic, demand and sales data. The selection of these five countries was executed according to a well-considered logic: the selection of countries covers Member States with, on the one hand, a considerable population size only and on the other, different situations with respect to the regulatory status. In this respect the Availability Survey reflects the diversity of the regulatory environments of the EU.

The availability of homeopathic medicinal products may be limited by different factors as follows:

5.3.1 Limitations on availability caused by the absence of authorised products in a country

Limitation of availability might result from the lack of a legal or regulatory base for the products, and/or from the absence of authorised products for economic reasons (if the effort for the submission and maintenance of dossiers for the products is not profitable). As these two factors cannot be clearly separated, they will be further discussed together. In the following we will first address the general information on availability resulting from sales data and then check it against examples from the results of the Availability Survey.

i. **The legal limitation of incomplete implementation of Article 16.2 of Directive 2001/83/EC**

The consistent nature of the results of the Availability Survey, despite the different country profiles, seems to justify a generalisation across the EU of the demand for availability of homeopathic or anthroposophic specialities with an indication. As discussed above, demand was visible (and met) in all five Member States, independently of both the legal/regulatory situation and the country profile with respect to figures of

³⁸ European Committee for Homeopathy: Contribution to discussion at homeopathic workshop at EMEA on 27th October 2006. Available from www.ema.europa.eu/docs/en_GB/document_library/Presentation/2009/11/WC500012296.pdf [quoted 05.04.12]

prescribers and sales data. If this demand is accepted as a more or less general demand across the EU, a legal/regulatory limitation for the availability of this type of products exists in all countries where article 16.2 is not implemented or not fully executed.

ii. The legal limitation of missing legislation for anthroposophic medicinal products

In the EU Member States, the availability of anthroposophic medicinal products is limited by a lack of general regulation, for those products which are not covered by the rules for homeopathic medicinal products.

iii. The regulatory burden for dossiers

Up to 3,000 different stocks are presented as essential for the prescribers to allow them to practise homeopathy in a proper way.³⁹ A high number of stocks are also required for anthroposophic medicine;⁴⁰ a large number of these products are not regularly prescribed and therefore show an extremely low rotation. This means that where the demand is prescriber-driven, the burden for the establishment and maintenance of registrations and marketing authorisations presents a permanent threat to the whole lifecycle of products. An additional and disproportionate regulatory burden in a number of countries may arise if there is limited interest in or knowledge of homeopathy or anthroposophic medicine by the competent authorities.

The comparison of the data on the regulatory status of HAMPs in the different Member States with the sales figures or numbers of homeopathic prescribers provides the following analysis:

- in at least three Member States of high or average sales data, the availability of HAMPs is still based on transition rules, without any progress in the assessment of registration dossiers (Belgium, Italy, Spain)
- in several other Member States, the registration figures indicate an on-going but slow registration process
- in several Member States with high, average or at least considerable numbers of homeopathic prescribers, no registrations exist according to Article 14 (Bulgaria, Slovenia) nor does the number of final registrations in any way reflect the needs of prescribers for a large number of available stocks (Ireland, Finland, UK)
- as regards some new Member States, it has to be considered that if no registrations existed from the period before EU access, it is not realistic to expect them to have caught up within ten years with what the older Member States have not achieved in almost twenty.⁴¹

iv. The economic burden resulting from registration

This regulatory burden finds its economic expression in relatively high costs for registration and dossier maintenance. This is relevant both for applicants and competent authorities. It weighs heaviest in the smaller markets. Where this is due to the size of the country, the problem applies to all categories of medicinal products and has been recognised by the EU legislators in Article 126a of Directive 2001/83/EC (the 'Cyprus clause').

Markets may also be small due to low sales (for example Hungary, Romania, Czech Republic and Slovakia, which are nevertheless characterised by a high visible demand for HAMPs as demonstrated by the figures of homeopathic prescribers). The sales data of these countries do not justify the economic effort of the establishment and maintenance of hundreds to thousands of dossiers.

In all Member States where final registrations do exist, the increasing administrative burden for dossier maintenance represents a continuous threat to a sustainable availability with respect to the numbers of dossiers and sales. This, again, is especially true for the smaller markets.

³⁹ European Committee for Homeopathy: Contribution to discussion at homeopathic workshop at EMEA on 27th October 2006. Available from www.ema.europa.eu/docs/en_GB/document_library/Presentation/2009/11/WC500012296.pdf [quoted 05.04.12]

⁴⁰ Anthroposophic Pharmaceutical Codex – APC - Part IV appendices starting materials list www.iaap.org.uk/downloads/codex.pdf [quoted 05.04.12]

⁴¹ Directive 92/73/EEC was published in the OJ on 13 October 1992; the deadline for implementation by the Member States was 31 December 1993

The results of this report indicate a certain trend that shows that significant OTC- or self-medication based sales of HAMPs in a Member State may correlate with a better regulatory situation. Two findings, one in new markets and one in markets with a long-term regulatory tradition, support this trend:

- firstly the situation found in Bulgaria, Latvia and Lithuania, for example, demonstrates that between 50 and 100 marketing authorisations (with a therapeutic indication) can be considered sufficient to cover a demand for homeopathic medicinal products for self-medication in general;
- secondly, the situation found in Austria, Germany and France is characterised by a practice of self-medication (or homeopathic treatment of minor conditions through self-selection from a popular publication or by recommendation from a pharmacist specialised in homeopathy) based on single remedies (without indication)⁴² together with a practice of use of homeopathic specialities authorised with an indication. This broad practice of self-medication comes together with a long-term regulatory tradition.

For both scenarios, the sales of HAMPs seem to better justify the economic burden for registration and dossier maintenance. This means that positive market developments in this sector are related to good regulatory practice.

v. Check against survey results

The general picture discussed above is confirmed by the results of the PwC Availability Survey. The availability was best in Germany and France for all types of products examined by the survey. As regards the situation in the Member States of the EU 15 (pre-2004), France and Spain, not all products provided by the pharmacies carry an authorisation number, which means that they are still not finally authorised. This puts into question, as a matter of principle, the sustainability and the current quality of the availability. While in France the re-registration is progressing with an official time table and official transition regulations are in place until final registrations are complete, in Spain the process has not yet been initiated.

Regarding the situation of the 'younger' EU Member States with a shorter history of regulatory practice following the EU Directive and its provisions for homeopathic medicinal products, in Bulgaria, homeopathic specialities with indications were available and their authorisation numbers are matched by an implementation of Article 16.2 in this country as well as marketing authorisations published by the agency. On the other hand no pharmacy was able to provide the homeopathic single remedies Pulsatilla and Formica rufa. At a first glance this might be related to a lack of registration, as the information of the webpage of the Bulgarian medicines agency webpage seems to illustrate. However, in a few cases other industrial homeopathic single remedies with no registration number were provided by the pharmacist in response to the request for a homeopathic medicinal product for a concrete treatment condition. The complete situation is not transparent, because according to ECHAMP internal knowledge, registrations of homeopathic single remedies do exist in Bulgaria. In Romania most homeopathic medicinal products were provided; unfortunately, the validation of the presentation with respect to regulatory compliance by a qualified person was not possible in this country for logistic reasons. Independent of this lack of confirmation, the regulatory status of the products is not transparent as a matter of principle: according to the webpage of the Romanian agency homeopathic medicinal products are authorised. However, on the one hand, there seems to be one registration number for sets of single remedies while on the other, the specialities with indication are authorised and available, although Article 16.2 of the Directive, the usual legal base for the authorisation of homeopathic specialities with indication, is not implemented in this Member State.

Obvious limitations by regulatory factors were found for anthroposophic medicinal products not available in Romania or Bulgaria, although anthroposophic medicine is practiced in both countries. In Romania, this might be caused by a lack of implementation of Article 16.2 of Directive 2001/83/EC into national law.

⁴² European Committee for Homeopathy: Practice: FAQ [Internet]. Available from www.homeopathyeurope.org/Practice/faq [quoted 11.04.12]. Steven Kayne: Homeopathic Pharmacy: theory and Practice. 2nd Edition. Edinburgh; 2006

5.3.2 Limitations on availability caused by deficiencies in the distribution chain

Depending on the efficiency of the national distribution system, the results of the Availability Survey show that the products with small rotation present a challenge: limitations became visible if the ordering time for products not in stock in the pharmacy was too long or if there were differences with respect to direct availability/ordering time between the different outlets of one country, or where data collectors were sent to other pharmacies. Such limitations were identified in France, Romania and in Spain. They particularly apply to prescriber-driven demand, mostly represented by the more rarely used homeopathic single remedies without indication, in the survey *Formica rufa*, or the anthroposophic medicines (where legally available as in France and Spain).

5.3.3 Consequences of limitations on availability

Patients who demand specific medicinal products which are not covered by any registrations may react in any of the following ways, leading to major public health concerns. They may:

- buy HAMPs outside the legal supply chain or via internet, often from non-EU countries
- substitute the products prescribed by their practitioners with 'similar' products
- be treated with products not subject to the European pharmacovigilance system
- simply not find their HAMP and stop the medicinal treatment
- receive the HAMPs with a significant delay because of availability problems.

As long as products are legally available under transition rules but not yet finally evaluated, there is a risk that patients will be treated with unauthorised products for which insufficient information exists and quality and safety are not guaranteed. On the other hand, upcoming dossier evaluation processes present a threat to sustained availability because no guarantee is given as to whether it will ultimately be logistically possible (for agencies and companies) to execute the registration work for all products on the market.

In summary:

The deficits of the implementation of the rules for homeopathic medicinal products in the EU Member States which are relevant to availability, and the resulting needs, are summarised as follows:

- i. The burden for the establishment and maintenance of registrations and marketing authorisations presents a permanent threat to the whole lifecycle of products. This applies predominantly to prescriber-driven therapeutic demand where a very high number of HAMPs is essential for the special nature of homeopathic and anthroposophic therapy and for the quality of the individualised therapeutic approaches. The reasons for this threat should be clearly identified in the different steps of the registration process and the resources and competencies needed for assessment work should be taken into account. To date, the process of mutual recognition/decentralised procedures is insufficiently simple or efficient to solve this issue.
- ii. For Article 14 applications, there is a lack of harmonisation of assessment amongst the Member States. Improvement will be essential both to limit the administrative burden and to reduce the efforts required by applicants and competent authorities to a level which is proportionate to the purpose.
- iii. The lack of implementation and execution of adequate rules following Article 16.2 of the Directive presents a threat to the guarantee to be able to comply with the demand that is clearly visible for HAMPs in OTC- and self-medication. The availability of a sufficient number of products with an indication is far from complete across the Member States of the EU. A more harmonised regulatory approach and assessment policy amongst the Member States will be needed to make progress in this respect and to meet the demand of citizens for self-medication with HAMPs in a single market situation.

iv. Regulatory, or where needed legislative, solutions based on a specific approach should be found so as to meet the growing demand for anthroposophic medicine and the corresponding medicinal products.

Future initiatives to improve the situation should discuss these deficits and look for adequate and proportionate solutions.

6. Conclusion

6.1 The demand for HAMPs in the EU

- A high to modest demand for homeopathic and anthroposophic medicinal products (HAMPs) is made visible in two thirds of EU Member States.
- The growth of the demand is significant in countries both with and without a long term tradition of homeopathy or anthroposophic medicine.
- The factors driving this demand (prescriber-driven demand versus OTC- or self-medication) are highly heterogeneous in the different countries.
- The Availability Survey consistently demonstrated that the best direct availability of products in the pharmacy outlets was for those requested by the customer to the pharmacist for self-medication.

6.2 Regulatory status of HAMPs in the EU

- There is a lack of full transparency as regards the regulatory status of HAMPs 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, almost **twenty** years after the publication of the specific Directive 92/73/EEC on homeopathic medicinal products, consolidated within Directive 2001/83/EC in 2001.
- 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

6.3 The availability of HAMPs in the EU

- In various Member States the availability of HAMPs is threatened by the lack of registration, or by an incomplete or outstanding re-registration process.
 - The availability of HAMPs for OTC- or self-medication is limited by incomplete implementation and execution of Article 16.2 of Directive 2001/83/EC
 - The availability of non-homeopathically produced anthroposophic medicinal products is limited due to the lack of legal provisions in the EU
 - In many Member States the demand expressed in terms of the numbers of homeopathic prescribers is not reflected in the numbers of registrations.
- The regulatory environment, including the assessment capacities and policy in the Member States, is not proportionate to the large range of stocks, and multiple finished HAMPs produced from these stocks, that are used in homeopathic and anthroposophic therapy.
- The need to maintain dossiers over the lifecycle for a large number of stocks will increasingly be challenged as long as the bureaucratic effort continues to grow. These efforts need to be multiplied over the number of Member States, while the sales of individual HAMPs are small. Where relevant figures of dossiers are needed in order to cover prescriber-driven demand, even if previous registrations do exist, the availability might not be sustainable due to the regulatory burden for maintenance.
- Higher proportions of sales carried by an OTC- or self-medication driven demand may support a better regulatory status.
- Depending on the distribution systems of the individual Member States, the availability in the distribution chain might be limited by the challenge to provide rarely sold but nevertheless essential remedies (single homeopathic remedies, anthroposophic remedies).