Survey on Homeopathic and Anthroposophic Medicinal Products

Regulatory Status – Survey Report

December 2010

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PRICEWATERHOUSECOOPERS

Disclaimer

This report represents the outcome of the survey sent to the Agency for Medicines and Health Products in each of the 27 EU Member States, complemented with desk research. The report was commissioned by ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) to have a clear overview on the status of the implementation of the pharmaceutical legislation (Directive 2001/83/EC) for the homeopathic and anthroposophic medicinal products (HAMP) in the 27 EU Member States with a focus on the “availability” and “freedom of choice” of these medicinal products.

Contents

Executive Summary

This report reflects the survey results based on data collected from the 27 EU Member States and Norway & Switzerland on registrations and marketing authorisations, the number of products notified, the extent of ongoing dossiers in the frame of a mutual recognition procedure and the number of staff engaged at the local authority. The objective of the survey is to have a clear overview on the status of the implementation of the pharmaceutical legislation (Directive 2001/83/EC) for the homeopathic and anthroposophic medicinal products (HAMP) in the 27 EU Member States.

The first two chapters discuss the number of homeopathic and anthroposophic medicinal products (HAMP) on the market in the different EU Member States. A significant range in the number of HAMP on the market in the different EU Member States is found. This is due to the fact that the EU Member States do not apply the same definition of HAMP. As a consequence, the exact number of HAMP present on the European market is difficult to assess due to variations between countries in the type (e.g. decimal, centesimal, Korsakov etc.) and the degree of dilution.

The third chapter focuses on the registration and notification of HAMP in the different EU Member States. Some countries are still in transition to implement the legal framework (Directive 2001/83/EC) on registration (Art. 14) and/or marketing authorisation (Art. 16.2) or have not yet enforced the law completely. In many countries, the implementation of Article 16.2 is still in a start-up phase. The survey indicated that the Czech Republic, Denmark, Portugal and Sweden have not yet implemented art.16.2 of Directive 2001/83/EC.

The fourth chapter focuses on the number of staff responsible for homeopathic and anthroposophic medicinal products in the different EU Member States Medicines Agencies. Many Medicine Agencies do not have specific departments dealing with homeopathic and anthroposophic medicinal products or do not have dedicated scientists for this type of medicinal products. As a consequence, responsibilities are often not segregated between this type of medicinal products and others. Therefore, it is difficult to assess the exact number of FTE involved in dealing with the homeopathic and anthroposophic medicinal products.

It should be noted that this report is based on the results collected from 15 participating Medicines Agencies.

1. Introduction

There is increasing visibility of complementary medicine and homeopathic and anthroposophic medicinal products (HAMP) in the media and in public discussions and these products are also formally or informally on the agenda of the various European institutions. The objective of the legislation in the European Union in general is to develop and implement an appropriate legal and regulatory framework in order to achieve free and easy availability of these medicinal products, and to ensure the products meet the highest standards of quality, safety and effectiveness, within the Community. This is clearly expressed in the two relevant documents of legislation as well as in the Commission report from 1997.[1,2]

Due to the fast-growing demand for these products as expressed by the Commission[2] and the Parliament[3] and as shown in different surveys[4], it is clear that there is an urgent need for the politicians and policy makers to move from a position of awareness and understanding to concrete action in favour of these well-established European therapies[5] and the special types of medicinal products they use.

As such, ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) requested PricewaterhouseCoopers to conduct a survey in order to collect data from the 27 EU Member States on the status of implementation of the pharmaceutical legislation (Directive 2001/83/EC) for the homeopathic and anthroposophic medicinal products. The aim of the survey is to have a better view on the regulatory situation in each country with respect to the ”availability” and “freedom of choice” of homeopathic and anthroposophic medicinal products.

The origin of this survey was the meeting between ECHAMP and the Belgian Health Minister, Mrs. Laurette Onkelinx. The Minister suggested to do a survey as a non-official initiative during the Belgian EU Presidency (1st July until 31st December 2010) in order to have a clear and objective picture of the current situation of HAMP in the EU market. In May 2010, this position was confirmed by the Head of the Belgian Medicines Agency. Even so the European Commission, DG Sanco C8 Pharmaceuticals, and the Cabinet of the Commissioner in charge, Mr. John Dalli, recently expressed their interest in information on the current status on the “availability” and “freedom of choice” of HAMP in the Member States.

Based on the outcome of the survey, it could be argued that there is a need to identify good practices with respect to the “availability” and “freedom of choice” of HAMP. These good practices could be rolled out across EU Member States.

The next four sections of the report correspond to the topics addressed in the survey (see Annex A: Questionnaire).

[1] Directive 2001/83/EC – Community code relating to medicinal products for human use
[2] Homeopathic Medicinal Products, Commission report COM(1997)362 – final on the application of Directives 92/73/EEC and 92/74/EEC
[3] European Parliament Report A4-0378/98 on Commission report COM(1997)362, November 1998
[4] Selection from a range of recent surveys:
- Eurispes – Rapporto Italia 2010 (scheda 55) – Curarsi con le medicine non convenzionali
- Scandinavian Journal of Primary Health Care – Scandinavian Journal of Primary Health Care, March 2005
- Complementary and Alternative Medicine in the UK and Germany – Research and Evidence on Supply and Demand, 2003
- Awareness, use and image of homeopathic medication in Germany, Allensbach Institute, 2009
- Non-conventional medicine in Italy: the present situation – Integrative Medicine, April 2009
- Sondage exclusif MEDECINE DOUCE/IFOP “les Français et les médecines naturelles”, November 2007

[5] http://www.camdoc.eu/Survey/Introduction.html

2. Approach to the survey

This paragraph describes the process of drafting the survey, all the way to the point of reporting the survey results. The figure below indicates the five steps in our approach:

Step 1: Request to launch the survey

On June 2010, ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products) and PricewaterhouseCoopers (PwC) met to discuss the objective of a survey on homeopathic and anthroposophic medicinal products and the design of the survey. Subsequently, ECHAMP selected PwC to perform an independent survey on homeopathic and anthroposophic medicinal products in the 27 EU Member States.

Step 2: Draft & approve the survey

ECHAMP provided a first draft of the questionnaire to PwC. This first draft had already been discussed with the Federal Agency for Medicines and Health Products (FAGG-AFMPS) in Belgium. Together with ECHAMP, PwC reviewed and adjusted the questions in order to obtain answers that would reflect the current situation on the registration of homeopathic and anthroposophic medicinal products in the European market.

Step 3: Launch the survey

Once the questions were validated and approved by ECHAMP, PwC programmed the questions in an online web-based survey tool. Based on the contact list provided by FAGG-AFMPS, the questionnaire was sent out by e-mail to the different Medicines Agencies in the 27 EU Member States.

Step 4: Survey results follow-up

In order to maximise the response rate of the survey, several follow-up actions were taken. An overview of these actions and the related results can be found in the following table.

Actions taken	Number of answers received
Launch of the survey, 24 September	0
Request Emiel Van Galen (HMPWG) to promote participation on the survey, 4 October	3
Reminders sent to all 27 EU countries, 13 October	7
Call targets to actively invite for participation, 2 November	5
Total of answers received	15

Step 5: Report

The information gathered from the survey has been categorised in 4 chapters:

1. Homeopathic medicinal products
2. Anthroposophic medicinal products
3. Registration & Notification
4. The Medicines Agency in the different EU Member States

Besides collecting data via the survey, desk top research has been performed to add information.

For each of the chapters, we summarized the answers in an overview table. Below each table, the comments of the respondents have been included. The comments indicate why certain data could not be provided or how the data needs to be interpreted, or the comments from the EU Member State provide additional information.

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3. Homeopathic medicinal products

3.1 Introduction

Homeopathy is a system of complementary medicine in which a disease is treated by minute doses of substances that in large quantities would produce symptoms of the disease. This is the basic principle of homeopathy[6].

Homeopathy uses a specific terminology that is not always used consistently in the current official documents and monographs. The definition of the WHO enjoys considerable consensus, and is broad enough to encompass homeopathic medicines made and used according to well-established variations of the original philosophy of Hahnemann. In this respect the WHO refers to this therapeutic approach as “homeotherapy”, a reference name for all therapeutic approaches that have been developed from homeopathy as established by Hahnemann.[7]

In the European legislation (Article 1(5) of Directive 2001/83/EC as amended by 2004/27/EC) a homeopathic medicinal product is defined as: “any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles”.[8]

The first European Directives on medicinal products were published in 1965 and 1975. At that time homeopathic medicinal products were not yet covered in the legislation. The introduction of Directive 92/73/EEC[9] on homeopathic medicinal products (as codified in Directive 2001/83/EC)[8] brought the first changes to the regulatory landscape in the EU with respect to complementary and alternative medicinal (CAM) products. With the adoption of Directives on herbal medicinal products[10], and the amendments for homeopathic medicinal products[11], the EU showed its intention to intensify and improve harmonisation in this legislative field. The Commission recognised the consumer and prescriber demand for plurality of medicines and the need for a better legislation in the report published in 1997.[12]

Generally speaking, European legislation on medicinal products has the objective to ensure the quality, safety and efficacy of products. In its Preamble, Directive 2001/83/EC recognises and addresses the fact that the legal requirements for conventional medicinal products may not be appropriate for CAM products, due to fundamental differences in terms of the nature of the products as well as due to their long-standing tradition of safe use.

[6] www.mhra.gov.uk
[7] Safety issues in the preparation of homeopathic medicines – WHO, 2009
[8] Directive 2001/83/EC – Community code relating to medicinal products for human use
[9] Council Directive 92/73/EEC widening the scope of Directives 65/65/EEC and 75/319/EEC
[10] Directive 2004/24/EC amending Directive 2001/83/EC
[11] Directive 2004/27/EC amending Directive 2001/83/EC
[12] Homeopathic Medicinal Products, Commission report COM(1997)362 – final on the application of Directives 92/73/EEC and 92/74/EEC

3.2 The survey results

Table 1: Survey results relate to the estimated number of finished homeopathic medicinal products – for single or complex remedies – on the market in the different EU Member States, whatever the status may be: registered, authorised, notified or grandfathered products and others[13]

27 EU Member States	# of finished homeopathic medicinal products on the market[14]	Estimated # of products for single* remedies[15]	Estimated # of products for complex* remedies[16]
Austria			
Belgium	15.000	2.300	5.120
Bulgaria			
Cyprus	0	0	0
Czech Republic	316	287	29
Denmark	Maybe 5.000	Unknown	Unknown
Estonia			
Finland	505	307	198
France			
Germany			
Greece			
Hungary			
Ireland	Unknown	Unknown	Unknown
Italy	Around 31.000	Around 9.000	Around 22.000
Latvia	111	Unknown	93
Lithuania			
Luxembourg			
Malta			
Netherlands	3.800	3.500	300
Poland			
Portugal	846	536	310
Romania			
Slovakia			
Slovenia			
Spain			
Sweden	Approx. 1.200	Unknown	Unknown
United Kingdom	759	Unknown	Unknown
Other countries that were invited to participate in the survey			
Norway	Unknown	Unknown	Unknown
Switzerland	More than 20.000	More than 17.000	More than 3.000

[13] Non responding countries: Austria, Bulgaria, Estonia, France, Germany, Greece, Hungary, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain
[14] Question 6 from the survey (see Annex A)
[15] Question 7 from the survey (see Annex A)
[16] Question 8 from the survey (see Annex A)

Definitions*

Single remedy: means only one remedy at a time is prescribed to the patient. It is a form of homeopathy in which the remedy consists of highly diluted animal, drug, plant, or mineral substance that most closely matches the essence of the disease and the totality of symptoms. (Source: http://www.xs4all.nl/~healings/SingleRem.html & http://medical-dictionary.thefreedictionary.com)

Complex remedy: a system of homeopathic medicine that has more than one remedy combined together in one dosage form. (source: http://medical-dictionary.thefreedictionary.com)

Comments provided by the participating Medicines Agencies:

- **Belgium**: The data is an estimate based on the notifications made in January 2003 (result: 18.000 notifications). However, since then, some companies have discontinued their manufacturing and distribution activities. It must be noted that for the single remedies, the estimated number is an approximate number of stocks already notified (same for various companies and without any update), and that some companies seem to reduce the list of available remedies. For the estimation of single remedies (finished products), the Belgian Medicines Agency took into account the large number of possible combinations of stock/pharmaceutical forms and the type and degree of dilution (see Article 15 of Directive).
- **Cyprus**: There are no registered homeopathic medicinal products in Cyprus.
- **Czech Republic**: The numbers of all products may differ according to the applications submitted for renewals. Example: Belladona 5CH-30CH with up to eight different dosage forms.
  The figure 316 refers to the number of registrations and the figure 287 refers to single remedies (if different dosage forms and groups of dilutions for single products are included the figure is 3.858).
- **Finland**: Only the number of the homeopathic medicinal products that have been granted approval in Finland, whether registered or authorised, are known.
- **Portugal:** 846 (830 SR + 16 MA) Homeopathic Medicinal Products (HMP). This is the number of authorised HMP that are allowed on the market. There are still 400 Homeopathic Medicinal Products for Single Remedies (HMPSR) to assess, which, according to a transitory period, can stay in the market until assessment is finished. From these 830 HMPSR, 536 are unitary HMP and this number is calculated considering only the stock (and not the dilutions associated with the stock). Normally, in unitary HMPs, the dilutions 2CH-200CH; 4DH-60DH; 6K, 12K, 30K, 200K, 1000K, 10 000K, 50 000K and 100 000K are associated to each stock in each of the pharmaceutical forms and presentation/packaging. Therefore if all these items are combined (stock + pharmaceutical form + presentation/packaging + dilutions) there are 100 HMP instead of 1. Therefore, the number of unitary HMP will be 536 000 for single HMP.
- **Switzerland**: For single remedies all potencies made from the same starting material and in the same pharmaceutical form are counted as one single product. In the application procedure according to Section 5 of the Ordinance[17], no distinction is made between powder, tablets and drops. These dosage forms are also counted as one single product.
  All diluted versions of a single remedy on the market, are counted as one single product on the market.
- **United Kingdom**: This figure includes all Product License of Rights (PLRs) that are currently valid in the UK. Some of these PLRs could be considered homeopathic in accordance with the Directive and some may not. It would take a lot of time for the Medicines and Healthcare products Regulatory Agency (MHRA) to calculate the exact number of single and complex products. However, the MHRA is confident to state that the majority are single remedies.

3.3 Conclusion

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Key conclusions on homeopathic medicinal products.

- When comparing the number of finished homeopathic medicinal products on the market amongst the different EU Member States, a significant range is found: e.g. Italy reports the highest number of finished homeopathic medicinal products on the market 31.000 products, Belgium has 15.000, Sweden has 1.200 while Cyprus has none. This is due to the fact that the EU Member States make different interpretations of a “finished homeopathic medicinal product”.
- The exact number of finished homeopathic medicinal products (including the grandfathered products) present on the market is difficult to assess due to variations between countries in the type (e.g. decimal, centesimal, Korsakov etc.) and the degree of dilution.
- A lot of the products were on the market in the member states before 31.12.1993, covered by a registration or authorisation granted in accordance with national legislation which is fully in line with the provision of Article 13.1 of Directive 2001/83/EC (the so-called “grandfathered products”). For the grandfathered products, notification and registration was granted automatically.
  A product that is grandfathered is one that has been granted marketing authorization because it was already being marketed at the time the marketing authorization system was established. Therefore, these grandfathered products do not need to obtain a new marketing authorization under Directive 2001/83/EC.

[17] Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products - 22 June 2006

4. Anthroposophic medicinal products

4.1 Introduction

“Anthroposophic medicine is a complementary medicine that integrates theories and practices of modern medicine with alternative, nature-based treatments, including the use of homeopathic medicines and physical therapies. The approach regards human wellness and illness as biographical events connected to the body, soul and spirit of the individual. Anthroposophic medicine uses a holistic approach that focuses on factors that support human health, rather than on factors that cause disease, and also focusing on strengthening both the patient's body and individuality”[18].

The Anthroposophic Pharmaceutical Codex as well as the official monograph “homeopathic preparations” of the Swiss Pharmacopoeia and the working principles of anthroposophic medicinal products can be found on the website of the International Association of Anthroposophic Pharmacists (IAAP).[19]

Anthroposophic medicinal products have been largely addressed in a recent Commission report: “Anthroposophic medicine has been established in Europe since 1920. It is practised in Germany, the Netherlands, the UK, Italy, Spain, Poland and France, among others. It follows a global therapeutic approach that embraces the individual as a whole taking into consideration both the personality and the body. Anthroposophic products are designed to stimulate the patient’s powers of self-healing and use mineral, vegetable, metal and animal based raw materials. They can be used in every form of dosage and administration, including the external, internal and parenteral routes”.[20]

The same Commission report stresses in its conclusions:
“Medical traditions – such as anthroposophic, Ayurvedic and traditional Chinese medicine – are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices”.

[18] http://en.wikipedia.org/wiki/Anthroposophical_medicine
[19] http://www.iaap.org.uk/publications/index.html
[20] Communication COM(2008) – 584 – final on the specific provisions applicable to traditional herbal medicinal products

4.2 The survey results

Table 2: Survey results relate to the estimated number of finished anthroposophic medicinal products – for single or complex remedies – on the market in the different EU Member States, whatever the status may be: registered, authorised, notified or grandfathered products and others[21]

27 EU Member States	# of finished anthroposophic medicinal products on the market[22]	Estimated # of products for single* remedies[23]	Estimated # of products for complex* remedies[24]
Austria			
Belgium	1.316	1.250	66
Bulgaria			
Cyprus	0	0	0
Czech Republic	0	0	0
Denmark	Unknown	Unknown	Unknown
Estonia			
Finland	109	36	73
France			
Germany			
Greece			
Hungary			
Ireland	Unknown	Unknown	Unknown
Italy	Unknown	Unknown	Unknown
Latvia	Unknown	Unknown	Unknown
Lithuania			
Luxembourg			
Malta			
Netherlands	Unknown	Unknown	Unknown
Poland			
Portugal	2	0	2
Romania			
Slovakia			
Slovenia			
Spain			
Sweden	Unknown	Unknown	Unknown
United Kingdom	362	Unknown	Unknown
Other countries that were invited to participate in the survey			
Norway	Unknown	Unknown	Unknown
Switzerland	Approx. 2.200	Approx. 700	Approx. 1.500

[21] Non responding countries: Austria, Bulgaria, Estonia, France, Germany, Greece, Hungary, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain
[22] Question 10 from the survey (see Annex A)
[23] Question 11 from the survey (see Annex A)
[24] Question 12 from the survey (see Annex A)

Definitions*

Single remedy: means only one remedy at a time is prescribed to the patient. It is a form of homeopathy in which the remedy consists of highly diluted animal, drug, plant, or mineral substance that most closely matches the essence of the disease and the totality of symptoms. (Source: http://www.xs4all.nl/~healings/SingleRem.html & http://medical-dictionary.thefreedictionary.com)

Complex remedy: a system of homeopathic medicine that has more than one remedy combined together in one dosage form. (source: http://medical-dictionary.thefreedictionary.com)

Comments provided by the participating Medicines Agencies:

- **Belgium**: The data is an estimate based on the notifications made in January 2003. However, since then, some companies have discontinued their manufacturing and distribution activities. It must be noted that for the single remedies, the estimated number is an approximate number of stocks already notified (same for various companies and without any update), and that some companies seem to reduce the list of available remedies. For the estimation of single remedies (finished products), the Belgian Medicines Agency took into account the large number of possible combinations of stock/pharmaceutical forms and the type and degree of dilution (see Article 15 of 2001/83/EC): around 450 have been notified (considering an average of 5 combinations for half of the notified single remedies but this is just a hypothesis).
- **Cyprus**: There are no anthroposophic medicinal products.
- **Czech Republic**: There are no registered anthroposophic medicinal products.
- **Finland**: This is the number of the anthroposophic medicinal products that have been granted approval in Finland, whether registered or authorised.
- **Latvia**: The State Agency of Medicines of Latvia (SAM[25]) has not granted any authorisation or registration for anthroposophic medicinal products.
- **Sweden**: Anthroposophic medicinal products in general are not controlled by the competent authority (Medical Products Agency) in Sweden, except a few products. Anthroposophic medicine is only allowed to be practised within the context of a particular clinic (Vidarkliniken, Sweden). In Sweden the anthroposophic clinic (Vidarkliniken) has a permit from the Minister of Social Affairs, but doctors are only allowed to practise anthroposophic medicine if they do so at, or in connection with the Vidarkliniken.
- **Switzerland:** For single remedies all potencies made from the same starting material and in the same pharmaceutical form are counted together as one single product. In the application procedure according to Section 5 of the Ordinance[26], no distinction is made between powder, tablets and drops. These dosage forms are also counted as one single product.
  All diluted versions of a single remedy on the market, are counted as one single product on the market.
- **United Kingdom**: These all currently exist as PLRs. It would take a lot of time for the MHRA to calculate the exact number of single and complex products. However, the MHRA is confident to state that the majority are single remedies.

4.3 Conclusion

Key conclusions on anthroposophic medicinal products.

- Potential reasons why countries might not know the number of finished anthroposophic medicinal products on their market:
  - anthroposophic medicinal products have no harmonised definition in the EU
  - anthroposophic medicinal products in general are not controlled by the competent authority (e.g. Sweden)
  - the competent authority does not grant any authorisation or registration for anthroposophic medicinal products (e.g. Latvia)
- The number of finished anthroposophic medicinal products for single or complex remedies is difficult to be provided. This is related to different interpretations of what a finished anthroposophic homeopathic medicinal product is.
- The exact number of finished anthroposophic medicinal products (including the grandfathered products) present on the market is difficult to assess due to variations between countries in the degree of the decimal dilution. Therefore, when comparing the number of finished anthroposophic medicinal products on the market among the countries, a significant range is found: Switzerland reports the highest number of finished anthroposophic medicinal products on the market: 2.200 products. There is a high number as well for Belgium: 1.316 products while Cyprus and the Czech Republic have none.
- Most of the finished anthroposophic medicinal products on the market in the United Kingdom have a so-called Product License of Right (PLR) since 1972 (grandfathered status).
- Some countries do not make a distinction between homeopathic and anthroposophic medicinal products. As a consequence, the data provided by the different countries can not be compared.

[25] SAM is the Regulatory Authority under direct jurisdiction of the Ministry of Health. The objective of the Agency is ensuring availability of efficient, safe and qualitative medicines to the Latvian population.
[26] Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products - 22 June 2006

5. Registration & Notification

5.1 Introduction

This chapter focuses on the registration and notification of HAMP. First, it explains the concepts of "Special Simplified Registration", "Full registration procedure" and "Market Notification" for homeopathic medicinal products. In the next section, the registration and notification for anthroposophic medicinal products is discussed. After the introduction, the survey results together with the conclusions are presented.

5.1.2 Homeopathic medicinal products

5.1.2.1. Registration

No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State[27]. After a marketing authorisation has been granted, the holder of the authorisation shall inform the competent authority of the authorising Member State of the date of actual marketing of the medicinal product for human use in that Member State, taking into account the various presentations authorised. The holder shall also notify the competent authority if the product ceases to be placed on the market of the Member State, either temporarily or permanently[28].

Member States shall ensure that homeopathic medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 14, 15 and 16 of Directive 2001/83/EC, except where such medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993.

The Directive 2001/83/EC on medicinal products for human use has introduced two procedures for market access of homeopathic medicinal products:

- Special Simplified Registration Procedure – Article 14 of Directive 2001/83/EC on medicinal products for human use
- Full registration procedure – Article 16 of Directive 2001/83/EC on medicinal products for human use

The special simplified registration procedure applies to medicinal products produced in accordance with a homeopathic manufacturing procedure which meet the following criteria:

- they are sufficiently diluted to guarantee their safety, they do not contain more than 1:10.000 part of the mother tincture or 1:100 part of the smallest dose of a substance that is used in allopathic medicine, and for which a doctor's prescription is required
- they are for oral or external administration
- they do not bear and cannot claim a specific therapeutic indication

The procedure is referred to as "simplified" because it requests fewer requirements for the admission of homeopathic medicinal products as compared to the regular procedure. In exchange, the products may not bear references of therapeutic efficacy on their labels or accompanying information. Since the procedure deviates from the "regular" authorisation procedure, it can furthermore be qualified as "special".

The full registration procedure needs to be used for products that do not meet the above criteria. They need to be authorized in accordance with Article 16. Under Article 16.1, the general licensing procedures for allopathic medicinal products are in principle applicable to homeopathically produced medicinal products that are not eligible for a special simplified registration.

[27] Article 6 of Directive 2001/83/EC
[28] Article 23a of Directive 2001/83/EC

The revision of Directive 2001/83/EC in 2003-2004 has resulted in a number of changes:

1. Directive 2003/63/EC has inserted specific provisions on the proof of quality and safety of homeopathic medicinal products in the amended Annex I of Directive 2001/83/EC providing more clarity for the assessment of applications.

2. The review process of Directive 2001/83/EC resulted in the adoption of Directive 2004/27/EC, which is a step forward regarding the inclusion of the mutual recognition and decentralised procedures. The scope of the mutual recognition and decentralised procedures is restricted to products entitled to a special simplified registration.

5.1.2.2. Notification

A Community Marketing Authorization is valid throughout the European Union and a centrally authorised medicinal product is therefore by definition identical in all Member States. As a consequence, products put on the market in one Member State can be marketed in any other part of the Community by a distributor ("parallel distributor") independent of the Marketing Authorisation Holder. The only changes parallel distributors may introduce to the packaging of a centrally authorised medicinal product are those which are strictly necessary to market the product in the Member State of destination.

At least 3 months prior to commencing distribution of a specific product, the parallel distributor sends the complete information (notification form) to the European Medicines Agency (EMEA) – Human or Veterinary Medicines Evaluation Unit –Parallel Distribution. Upon receipt of the notification, the EMEA will check its completeness and contact the applicant if any information is missing or incorrect.

When there are no objections or when objections have been completely addressed, the EMEA sends a notice to the parallel distributor, the Member State of destination and the Marketing Authorisation Holder of the medicinal product, indicating that the regulatory check has been completed[29].

5.1.3 Anthroposophic medicinal products

Within the framework of the EU pharmaceutical legislation, the legal status of anthroposophic medicinal products is less clear than that of homeopathic medicinal products. Medicinal products used within the anthroposophic medical tradition can, in most cases, not be distinguished on the basis of their methods of production, as these are largely shared with other medicinal product groups, such as homeopathic and herbal medicinal products. In the case of overlap, anthroposophic medicinal products are legally classified as homeopathic or traditional herbal medicinal products as mentioned in Articles 1(5) and 1(29) of Directive 2001/83/EC. Insofar as these specific categories do not apply and because of the absence of a specific definition of anthroposophic medicinal products in the European legislation these medicinal products can only be covered by the general definition of medicinal product as described in Article 1(2) of Directive 2001/83/EC.

The Member States show significant differences in the definition of anthroposophic medicinal products, as well as in their authorisation procedures, leading to trade barriers and legal uncertainty. In this context, the Draft Communication Report[30] from the Commission on specific provisions applicable to traditional herbal medicinal products does not lead to a harmonised solution on the basis of an "extension" of the "traditional use" registration in the coming years. The practical consequence of the latter is a de facto prohibition of non-homeopathic or non-traditional herbal anthroposophic medicinal products in certain Member States.

NOTE: the anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated in the same way as homeopathic medicinal products with respect to registration and marketing authorization[31].

[29] http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004972.pdf
[30] Communication from the Commission to the Council and the European Parliament, Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to traditional herbal medicinal products. Document on the basis of article 16i of Directive 2001/83/EC (http://www.echamp.eu/fileadmin/user_upload/Regulation/Draft_report_on_extension__traditional_use__registrations.pdf)
[31] Directive 2001/83/EC (22)

5.2 The survey results

5.2.1 General observations

Table 3: Survey results relate to notifications at the Medicines Agency.[32]

27 EU Member States	# of notifications for HAMP – simple or complex[33]	Does this notification list make a distinction between HAMP subject to Art. 14 – Registration and HAMP subject to Art. 16 – National Marketing Authorisation?[34]	Year of notification or any other "preliminary transition procedure"[35]	Are the lists of these notifications available?[36]
Austria				
Belgium	18.000	Distinction between complex and single remedies	January 2003	Yes
Bulgaria				
Cyprus	0	No	Unknown	No
Czech Republic	0	No	Unknown	No
Denmark	Maybe 5.000	No Art. 16 products	1998 and 2005	No
Estonia				
Finland	Unknown	No	Unknown	No
France				
Germany				
Greece				
Hungary				
Ireland	Confidential	Two separate schemes	2006 (Art. 16) and 2002 (Art. 14)	No
Italy	Around 31.000	No	1995 and 1997	No
Latvia	Unknown	No	Unknown	No
Lithuania				
Luxembourg				
Malta				
Netherlands	No notification system	No notification system	Notification ended in January 2002	Yes
Poland				
Portugal	3.300	Yes	1999/2000	Yes
Romania				
Slovakia				
Slovenia				
Spain				
Sweden	550	No	Unknown	Yes
United Kingdom	Unknown	No	Unknown	No
Other countries that were invited to participate in the survey				
Norway	Unknown	No	Unknown	No
Switzerland	5.827 (a)	Yes (b)	2002 (c)	Yes (d)

[32] Non responding countries: Austria, Bulgaria, Estonia, France, Germany, Greece, Hungary, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain.
[33] Question 14 from the survey (see Annex A)
[34] Question 15 from the survey (see Annex A)
[35] Question 16 from the survey (see Annex A)
[36] Question 17 from the survey (see Annex A)

Comments provided by the participating Medicines Agencies:

- **Belgium**: The list of products with market authorization has been previously available on the website of the Belgium Medicines Agency. Currently (April 2011) the website is no longer available, because an update is needed to reflect recent changes in products and companies. The new lists will be published on the website as soon as possible. The Belgium Medicines Agency is able to give information on notified medical products upon request.
- **Finland**: There is no notification system for homeopathic and anthroposophic medicinal products.
- **Netherlands**: The list with products notified by the Dutch manufacturers has been published by the Dutch Medicines Evaluation Board (MEB) in 1997 and 1998 (second edition) at SDU Publishers. The list contains more than 10.000 homeopathic medicinal products. No list for anthroposophic medicinal products is available.
- **Norway**: Art. 14 was implemented in the Norwegian legislation in January 2010, there is a transition period of 7 years. Currently, no applications have been received. The homeopathic and anthroposophic medicines may be sold through Norwegian pharmacies if they are registered in another EEA country. It is the wholesaler's responsibility to confirm the registration.
- **Portugal**: The number of notifications provided by Inframed (The Portuguese Medicines Agency) is related to the number of notifications received in the agency when the assessment of HAMP started. The list of notifications was published in Decreto Lei 94/95, May 9th.
- **Switzerland**:
  (a) In addition to the 5.827 notifications, there are a great number of homeopathic and anthroposophic products without an indication on the market according to the transitional provisions of Art. 33 of the Swiss Ordinance[37]. Up to now these products are notified but it's not possible to give an exact number. Most of these notifications will be transferred into registrations in the near future. Estimated number for these products: 11.000.
  (b)

	Products registered	Applications under assessment
In analogy with Art. 14		
- without indication # of products, administered orally or external	4.709	9.856
- without indication # of products, injections	438	177
In analogy with Art. 16		
- with indication # of products	680	4

  (c) - Before 2002 there was only mandatory authorisation for pharmaceutical specialities (specific brands and indication): One of the first registrations of homeopathic/anthroposophic products with indication was given in 1934.
  - On January 1, 2002 the Law on Therapeutic Products[38] came into force. It describes the rules for the authorization, production, quality control and market supervision of therapeutic products and for national and international cooperation between the authorities working in the therapeutic products sector. In the case of medicines, the new law enables the former cantonal regulations to be converted into federal legislation. Since 2002, Switzerland has a mandatory authorisation for homeopathic/anthroposophic products without indication.
  - A special guidance[39] for the homeopathic/anthroposophic products was provided in 2002.
  - In 2006 the Ordinance on Complementary and Herbal medicinal products enacted[40].
  (d) The lists cover the authorised products with and without indications. They do not cover the homeopathic and anthroposophic products which are still on the market according to the transitional provisions of Art. 33 of the Swiss Ordinance[40].
  Overall comments from Switzerland:
  The Directive 2001/83/EC is not applicable in Switzerland. Switzerland has its own regulations for homeopathic and anthroposophic medicinal products. But in analogy with the Directive, the Swiss Medicines Agency differentiates between products with and without indication. They can be found in the Ordinance on Complementary and Herbal medicinal products which is published on the Swissmedic Homepage: www.swissmedic.ch/KPA-Rechtstexte.asp[41].

[37] Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products - 22 June 2006
[38] The Swiss Federal Law on Medicinal Products and Medical Devices (known as the Law on Therapeutic Products)
[39] The Swiss Federal Law on Medicinal Products and Medical Devices
[40] Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products - 22 June 2006
[41] Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products - 22 June 2006

For single remedies all potencies made from the same starting material and in the same pharmaceutical form are counted together as one single product. In the application procedure according to Section 5 of the Ordinance[41] no distinction is made between powder, tablets and drops. These dosage forms are also counted as one single product.

- **Sweden**: Sweden considers products submitted for registration as "notified products". In Sweden, only Article 14 of Directive 2001/83/EC has been implemented. The products were notified in 1993 and will be completed (registered or rejected) no later than April 2011.
  Registration in Sweden complies with articles 14 and 15 of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code Relating to Medicinal Products for Human Use, as well as articles 17 and 18 of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products.
  As stated in the Medical Products Agency's Code of Statutes[42] homeopathic medicinal products must be registered at the Medical Products Agency in order to be sold on the Swedish market. The procedure for registering homeopathic products in Sweden differs depending on whether the application was received before or after 1 May 2006, at which time revised regulations took effect.
  *Applications for registration **before** 1 May 2006*: The revised legislation of 1 May 2006 imposed provisional regulations for homeopathic products, which are subject to special marketing authorisation while waiting for the Medical Products Agency to process the application (so-called free-listed homeopathic products). The provisional regulations forbid the sale of free-listed homeopathic products after 30 April, 2011. After that date, all homeopathic products must be reviewed and registered by the Medical Products Agency in order to be sold.
  *Applications for registration **after** 1 May 2006:* After 1 May 2006, registration applications for homeopathic medicinal products must be submitted to the Medical Products Agency in English in CTD format (Common Technical Document). A CTD-compliant application form can be downloaded from the European Commission's website.
- **United Kingdom**: There is no information available on notifications in the UK.

[42] http://www.lakemedelsverket.se/english/product/Homeopathic-products/Registration-of-homeopathic-medicinal-products/

5.2.2 Article 14 of Directive 2001/83/EC

Table 4a: provides an overview of the registration and notification of HAMP under article 14 of Directive 2001/3/EC[43].

27 EU Member States	# of registered products or products for which the registration procedure was started[44]	# of registered products[45]	# of applications[46]	Are lists of these products published or otherwise available?[47]	Registered authorized products[48]	Comments relate to information gathered from the websites
Austria					6209[49]	
Belgium	39	0	0	No	No data available[50]	
Bulgaria					65[51]	
Cyprus	Do not know	0	0	No		
Czech Republic	316 + 1 (pending registration)	316	1	Yes	258[52]	3414 registered products, of which 258 unique
Denmark	2-3 products	0	Unknown	No		3306 products, but it is not clear which are HAMP[53]
Estonia					22[54]	
Finland	12	12	37	No	181[55]	
France					173[56]	
Germany					2052[57]	Website provides overview of registered products, no detailed list available
Greece						

[43] Non responding countries: Austria, Bulgaria, Estonia, France, Germany, Greece, Hungary, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain.
[44] Question 19 from the survey (see Annex A)
[45] Question 21 from the survey (see Annex A)
[46] Question 22 from the survey (see Annex A)
[47] Question 23 from the survey (See Annex A)
[48] Based on information found on the website of the Medicine Agency
[49] http://www.basg.at/news-center/statistiken/arzneimittel-in-oesterreich/
[50] http://www.fagg-afmps.be/en/items/database/
[51] http://www.bda.bg/images/stories/documents/med_inf/OTC.pdf
[52] http://www.sukl.eu/modules/medication/search.php
[53] http://laegemiddelstyrelsen.dk/ftp-upload/ListeOverGodkendteLaegemidler.xls
[54] http://193.40.10.165/register/register.php
[55] http://www.fimea.fi/whats_new/1/0/
[56] http://www.afssaps.fr/Activites/Pharmacopee/Que-trouver-dans-la-Pharmacopee-francaise/(offset)/3
[57] http://www.bfarm.de/DE/Home/home_node.html

27 EU Member States	# of registered products or products for which the registration procedure was started	# of registered products	# of applications	Are lists of these products published or otherwise available?	Registered authorized products	Comments relate to information gathered from the websites
Hungary					269[58]	3404 registered products, of which 269 unique
Ireland	Confidential	Approx. 43	Confidential	Yes	57[59]	
Italy	Unknown	Unknown	1	No		
Latvia	Unknown	Unknown	Unknown	No		
Lithuania						
Luxembourg						
Malta					No data available	List of products available, not clear which are HAMP[60]
Netherlands	3.183	3.183	Approx. 100	Yes	464[61]	
Poland					336[62]	578 registered products, of which 336 unique
Portugal	Approx. 830	Approx. 830	Approx. 400	Yes	832[63]	51212 registered products, of which 832 unique
Romania					48[64]	
Slovakia					110[65]	1036 registered products, of which 110 unique
Slovenia						List of products available, not clear which are HAMP[66]
Spain						

[58] http://www.ogyi.hu/drug_database/index.php
[59] http://www.imb.ie/images/uploaded/swedocuments/latestHMlist.pdf
[60] http://www.maltamedicineslist.com/
[61] http://www.cbg-meb.nl/NR/rdonlyres
[62] http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/urzedwpl_2009_czesc_1a_16062009.pdf
[63] http://www.infarmed.pt/portal/page/portal/INFARMED/
[64] http://www.anm.ro/app/nom1/anm_list.asp
[65] http://www.sukl.sk/en/servis/search/searching-on-the-database-of-medicinal-products
[66] http://www.jazmp.si/objave/eng/BPZ_eng.pdf

27 EU Member States	# of registered products or products for which the registration procedure was started	# of registered products	# of applications	Are lists of these products published or otherwise available?	Registered authorized products	Comments relate to information gathered from the websites
Sweden	Approx. 1.200	650	550	Yes	615[67]	1196 registered products, of which 615 unique
United Kingdom	317	262	55	Yes	285[68]	825 registered products, of which 285 unique
Other countries that were invited to participate in the survey						
Norway	Unknown	0	0	No		
Switzerland	No	N/A	N/A	N/A		

[67] http://www.lakemedelsverket.se/upload/halso-och-jukvard/homeopatika/gk_homreglista%20produktnamn.pdf
[68] http://www.mhra.gov.uk/index.htm

Table 4b: Survey results relate to the registration procedure of homeopathic medicinal products in accordance with Article 14 of Directive 2001/83/EC[69]

27 EU Member States	# of mutual recognition procedures in which the country has participated as a reference Member State[70]	# of mutual recognition procedures in which the country has participated as a concerned Member State[71]
Austria		
Belgium	0	0
Bulgaria		
Cyprus	0	0
Czech Republic	0	0
Denmark	0	0
Estonia		
Finland	0	0
France		
Germany		
Greece		
Hungary		
Ireland	0	0
Italy	0	1
Latvia	Unknown	Unknown
Lithuania		
Luxembourg		
Malta		
Netherlands	0	3
Poland		
Portugal	0	1
Romania		
Slovakia		
Slovenia		
Spain		
Sweden	0	0
United Kingdom	0	1
Other countries that were invited to participate in the survey		
Norway	0	0
Switzerland	N/A	N/A

[69] Non responding countries: Austria, Bulgaria, Estonia, France, Germany, Greece, Hungary, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain.
[70] Question 32 from the survey (see Annex A)
[71] Question 33 from the survey (see Annex A)

Comments provided by the participating Medicines Agencies:

- **Belgium**: The list of products for which the assessment procedure for a registration has been started is not published. If/when the registration is granted, products are published.
  Note that the number of registered products corresponds to single remedies as such taking into account Article 15 (possible combinations of pharmaceutical forms and type and degree of dilution), but it also includes remedies used in complex (cf. possibility of later cross reference) remedies.
  Some national applications for which a Mutual Recognition Procedure (MRP) should have been initiated and for which Belgium should have been a concerned Member State have been refused.
- **Czech Republic**: Lists of these products are available on the website of the State Institute for Drug Control. The published database contains all authorised/registered medicinal products including homeopathic products.
  All products registered in the Czech Republic were registered under the simplified procedure in accordance with Art.14 of Directive 2001/83/EC.
- **Finland**: 4 out of 12 products, for which the assessment procedure for registration had been started, were withdrawn.
- **Ireland**: The registered products are listed on the Irish Medicines Board (IMB) website. The products under assessment are not published. Approximately 43 products are registered while the others are under assessment. Ireland has not yet received a request to participate as a reference Member State or as a concerned Member State.
- **Latvia**: The State Agency of Medicines (SAM) has not yet granted any registration for homeopathic medicinal products subject to Art. 14 - Registration. There are no applications for the simplified procedure of homeopathic medicinal products.
- **Netherlands**: The “Lijst homeopathisch farmaceutische producten 2010” is available for downloading as a PDF at the Medicines Evaluation Board (CBG-MEB) website: http://www.cbg-meb.nl. The MEB assesses and monitors the efficacy, risks and quality of human and veterinary medicinal products. It also assesses the safety of novel foods for human consumption. No list for anthroposophic medicinal products is available.
- **Portugal**: Lists are available at the National Authority of Medicines and Health Products (Infarmed) website:
  http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AUTORIZACAO_DE_INTRODUCAO_NO_MERCADO/PRODUTOS_FARMACEUTICOS_HOMEOPATICOS
  Inframed is a Government agency accountable to the Health Ministry. The objective is to monitor, assess and regulate all activities relating to human medicines and health products for the protection of Public Health.
- **Sweden**: A few “new” applications that have not previously been notified are not part of the lists since they are not yet on the market. Only products legally marketed are on the lists.
  With respect to single component products, a series of dilutions is registered as one product (product group).
- **Switzerland:** The Directive 2001/83/EC is not applicable in Switzerland.
- **United Kingdom**: A list of products granted a registration under Article 14 of Directive 2001/83/EC can be provided by the MHRA upon request. Information about actual pending applications is confidential.

5.2.3 Article 16.2 of Directive 2001/83/EC

Table 5: provides an overview of the registration and notification of HAMP under article 16.2 of Directive 2001/3/EC[72].

27 EU Member States	Is a specific legal category in place in accordance with Art. 16.2 of Directive 2001/83/EC? [73]	# of products for which a national marketing authorisation has been given or the assessment procedure for a national marketing authorisation has been started[74]	# of products that have been granted a national marketing authorisation[75]	# of applications under assessment[76]	Are lists of these products published or otherwise available? [77]
Austria					
Belgium	Yes	35	1	34	Yes
Bulgaria					
Cyprus	No	Unknown	0	0	No
Czech Republic	No	Unknown	0	0	No
Denmark	No	Unknown	0	0	No
Estonia					
Finland	No	Unknown	Unknown	3	No
France					
Germany					
Greece					
Hungary					
Ireland	Yes	Unknown	0	Confidential	No
Italy	No	Unknown	Unknown	Unknown	No
Latvia	No	Unknown	Unknown	Unknown	No
Lithuania					
Luxembourg					
Malta					
Netherlands	Yes	Approx. 700	619	Approx. 80	Yes
Poland					
Portugal	Yes	0	0	0	No
Romania					
Slovakia					
Slovenia					
Spain					
Sweden	No	Unknown	0	0	No
United Kingdom	Yes	15	1	14	Yes
Other countries that were invited to participate in the survey					
Norway	No	Unknown	0	0	No
Switzerland	Yes		680	4	Yes

[72] Non responding countries: Austria, Bulgaria, Estonia, France, Germany, Greece, Hungary, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain.
[73] Question 25 from the survey (see Annex A)
[74] Question 27 from the survey (see Annex A)
[75] Question 28 from the survey (see Annex A)
[76] Question 29 from the survey (see Annex A)
[77] Question 30 from the survey (see Annex A)

Comments provided by the participating Medicines Agencies:

- **Belgium:** For the homeopathic medicinal products for which the "simplified registration procedure" is not applicable, the Minister of Health, after having received advise from the Commission for homeopathic medicinal products for human and veterinary use (HCG), identifies special rules concerning the implementation and evaluation of the clinical and preclinical testing procedures[78].
  The granted "Autorisation de Mise sur le Marché" (AMM) is published.
- **Czech Republic**: Currently, there is no specific legal category in place in accordance with Art. 16.2 of the Directive 2001/83/EE. Pharmaceutical companies have expressed the wish to change the situation.
- **Denmark**: Currently, there is no specific legal category in place in accordance with Art. 16.2 of the Directive 2001/83/EE. Some aspects of 16.2 are being discussed.
- **Ireland**: The National Rules Scheme for homeopathic medicines has been established according to Art. 16.2 in Ireland (S.I. 540 of 2007[79]). The deadline for receipt of applications under the National Rules Scheme is 30 September 2010.
- **Netherlands**: Article 42.4 of the Dutch Medicines Act ("Geneesmiddelenwet" published in July 2007[80]).
- **Portugal:** No marketing authorization has been granted according to article 16.2, only according to article 16.1. No assessment has been performed according to article 16.2. 15 HMP are under assessment according to Art. 136, nr. 5 of Decree Law 176/2006 dated August 30th[81]. Since there are no products assessed/registered according to art. 16.2, no product list exists. For the HMP authorized according to Art. 136 nr. 5 of Decree Law 176/2006, dated August 30th, products are listed in http://www.infarmed.pt/infomed/inicio.php
- **Sweden**: Article 16.2 has not been implemented.
- **Switzerland:** There are licensing procedures for all homeopathic and anthroposophic products which are defined in the Swiss Ordinance[82]. National marketing authorization is given according to the Swiss Ordinance. The list available at the Swiss Medicines Agency does not include the applications under assessment.
- **United Kingdom**: In the UK there is a National Rules Scheme, which has been established in the UK since 1 September 2006[83]. A list of products that have been granted authorisation under Article 16.2 can be provided by the MHRA upon request.

[78] Article 41 of the "Royal Decree dated 14/12/2006 on medicinal products http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&table_name=wet&cn=2006121431
[79] http://www.irishstatutebook.ie/2007/en/si/0540.html
[80] http://wetten.overheid.nl/BWBR0021505/geldigheidsdatum_04-02-2010
[81] http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/035-E_DL_176_2006_VF.pdf
[82] Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of complementary and herbal medicinal products - 22 June 2006
[83] http://www.mhra.gov.uk/Howweregulate/Medicines/Homeopathicmedicines/index.htm

5.3 Conclusion

5.3.1 General conclusions

Key conclusions on registration and notification – general observations:

- Some countries are still in the transition period to implement the legal framework on registration (Art. 14) and/or marketing authorisation (Art. 16.2) or have not yet enforced the law completely.
- In Norway, Article 14 was implemented in January 2010, with a transition period of 7 years. The homeopathic and anthroposophic medicines may be sold in Norwegian pharmacies if they are registered in another European Economic Area (EEA) country. It is the wholesaler's responsibility to confirm this.
- Sweden considers products submitted for registration as "notified products". In Sweden, only Article 14 has been implemented. The products were notified in 1993 and will be completed (registered or rejected) no later than April 2011.
- Switzerland has licensing procedures for all homeopathic and anthroposophic products which are defined in the Ordinance. There is a national marketing authorization according to the Swiss Ordinance for these products.
- In some countries homeopathic medicinal products have been notified but at the same time their presence on the national market is covered by a registration or authorisation granted in accordance with national legislation which is fully in line with the provision of Article 13.1 of Directive 2001/83/EC (the so-called "grandfathered products").
  Grandfathered products: a product that is grandfathered is one that has been granted marketing authorization because it was already being marketed at the time the marketing authorization system was established.
- Most of the countries have data on the amount of registrations and notifications but these are often difficult to consolidate. As a consequence it is not easy for those countries to provide an overview in an efficient and effective way. Some countries refer to their public domain website where (partial) information can be found. The data (statistics and product lists) that are available are mentioned in Annex C of this report.

5.3.2 Article 14 of Directive 2001/83/EC

Key conclusions with respect to the registration of HAMP under article 14 of Directive 2001/3/EC.

- In France there is an official list of 1163 homeopathic stocks since 1984. The products on this list are all fully registered. Homeopathic medicinal products based on these stocks are reimbursed. On the website of the French medicines Agency AFSSAPS there is a clear calendar for the applicants to introduce their dossiers up to December 31st, 2015. The calendar also indicates the progress that has been made with respect to the applications introduced. There is no information on the number of applications granted. http://www.afssaps.fr/var/afssaps_site/storage/original/application/d20337848f4a39c86c72fc6690529bf4.pdf
- In Germany, updated figures of registered homeopathic and anthroposophic medicinal products are published on the website of the German Medicines Agency BfArM as "Statitieken" http://www.bfarm.de/cln_094/DE/Arzneimittel/2_zulassung/zulArten/besTherap/allgemein/statistik-bescheidzahlen.html?nn=1009778
- In Sweden, a few "new" applications that have not previously been notified are not part of the list (list of products that have been granted a national marketing authorisation) since they are not yet on the market. Only products legally marketed are on the list. Also in Belgium and Ireland, products in an ongoing procedure/under assessment are not published, but once the registration is granted, the products will be published.
- Answers from the survey are in line with the information on the websites of the Medicines Agencies (references to these websites in appendix C).
- The Netherlands have participated three times as a concerned Member State in mutual recognition procedures for homeopathic medicinal products registered in accordance with Article 14. Italy, Portugal, Spain and the United Kingdom participated once as such, while the other countries that responded to the survey have never done so to date.

5.3.3 Article 16.2 of Directive 2001/83/EC

Key conclusions for the registration of HAMP under article 16.2 of Directive 2001/3/EC.

- On the website of the French medicines Agency AFSSAPS there is a clear calendar for the applicants to introduce their dossiers up to December 31st, 2015. The calendar also indicates the progress that has been made with respect to the applications introduced. http://www.afssaps.fr/var/afssaps_site/storage/original/application/d20337848f4a39c86c72fc6690529bf4.pdf. The decision of giving a marketing authorisation (AMM) to a homeopathic medicinal product is published in the French State Gazette (Journal Officiel).
- In Germany, updated figures of registered homeopathic and anthroposophic medicinal products are published on the website of the German Medicines Agency BfArM as "Statitieken" http://www.bfarm.de/cln_094/DE/Arzneimittel/2_zulassung/zulArten/besTherap/allgemein/statistik-bescheidzahlen.html?nn=1009778
- In many countries, Article 16.2 is in a start-up phase (some aspects are under discussion) or has not (yet) been implemented. The survey indicates that the Czech Republic, Denmark, Portugal and Sweden have not yet implemented art.16.2 of Directive 2001/83/EC.

6. The Medicines Agency in the different EU Member States and how it relates to homeopathic and anthroposophic medicinal products

6.1 Introduction

In each country, the Medicines Agency is responsible for the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The Agency is responsible for the scientific evaluation of applications for marketing authorisations for both human and veterinary medicines. The Agency constantly monitors the safety of medicines through a pharmacovigilance network, and takes appropriate actions if adverse drug reaction reports suggest that the benefit-risk balance of a medicine has changed since it was authorised. For veterinary medicines, the Agency has the responsibility to establish safe limits for medicinal residues in food of animal origin.[84]

Tasks of the Medicines Agencies are to[82]:

- provide independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines
- apply efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission
- implement measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks
- provide scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines
- recommend safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission
- involve representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest
- publish impartial and comprehensive information about medicines and their use
- develop best practice for medicines evaluation and supervision in Europe, and contribute to European cooperation of the Heads of Medicines Agencies (HMA)

The Heads of Medicines Agencies is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of Medicinal Products for human and veterinary use in the European Economic Area. The Heads of Medicines Agencies is supported by working groups covering specific areas of responsibility and by the Heads of Medicines Agencies Management Group and Permanent Secretariat.[85]

One of the working groups in the human medicines field is the Homeopathic Medicinal Products Working Group (HMPWG).[86] This group has a mandate since 2004. One of the ten points of the mandate is to develop the specific guidance environment for homeopathic medicinal products. The outcome of this work is published on the HMA website.

The ten points of the mandate of the HMPWG are[87]:

1. To create a forum for exchange of regulatory and scientific expertise regarding the assessment of the quality and safety of homeopathic medicinal products in the Member States
2. On request from Competent Authorities, to provide guidance on the assessment of homeopathic medicinal products
3. To provide guidance for applicants on the registration of homeopathic medicinal products
4. To establish one common dossier template for applications for the registration (Art. 14 of CD 2001/83/EC) of homeopathic medicinal products in the EU, in co-operation with the Notice to Applicants Group

[84] Source: http://www.emea.europa.eu
[85] Source and further info: http://www.hma.eu/
[86] http://www.hma.eu/79.html
[87] http://www.hma.eu/uploads/media/HMPWG_mandate_20.pdf

5. To provide advice and expertise, on request of the Coordination Group on procedural, regulatory and scientific issues arising from the mutual recognition and decentralised procedures applicable to homeopathic medicinal products
6. To facilitate the resolution of procedural, regulatory and scientific issues arising from variation procedures pertaining to homeopathic medicinal products
7. To support the drafting of a list of safe dilution grades for homeopathic products referred to in article 14 (1) of Directive 2001/83/EC
8. To address regulatory and scientific issues concerning homeopathic medicinal products on request by the European Commission, the Coordination Group, the Working Group for Homeopathic Medicinal Products (HoA) and the European Directorate for the Quality of Medicines & HealthCare (EDQM)
9. The WG shall draft rules of procedure for approval by HoA
10. Guidance documents, prepared by the Working Group, will be presented to the HoA Group for approval and publication on the HoA website

6.2 The survey results

Table 6: Survey results relate to the number of FTE in the department responsible for homeopathic and anthroposophic medicinal products in the different EU Member States[88]. The data in the table is based on the information obtained from the survey[89].

27 EU Member States	# of FTEs in the department responsible for homeopathic and anthroposophic medicinal products for the Medicines Agency
Austria	
Belgium	1,7
Bulgaria	
Cyprus	0,5
Czech Republic	0,4
Denmark	Unknown
Estonia	
Finland	3
France	
Germany	
Greece	
Hungary	
Ireland	1
Italy	Unknown
Latvia	Unknown
Lithuania	
Luxembourg	
Malta	
Netherlands	6
Poland	
Portugal	2,1
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	6,8
United Kingdom	2
Other countries that were invited to participate in the survey	
Norway	0
Switzerland	3,5

[88] Non responding countries: Austria, Bulgaria, Estonia, France, Germany, Greece, Hungary, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain.
[89] Question 35 & 36 in the survey (see Annex A)

Comments provided by the participating Medicines Agencies:

- **Belgium**: The Belgian unit is in charge of homeopathic (including anthroposophic) and herbal medicinal products. The FTE number provided includes a new FTE that started since 16/09/2010.
- **Czech Republic**: Both staff members are also responsible for other products (herbals and chemicals).
- **Ireland**: The Irish Medicines Board did not provide an answer to this question because many people in different departments are involved directly and indirectly in homeopathic medicines, e.g. Assessment, Safety and Compliance. Most people spend only a percentage of their time on homeopathic medicines. However, the Irish Medicines Board confirmed that there is one full-time employee who spends 100% of his time on homeopathic medicines.
- **Latvia**: SAM has no specific department of homeopathic and anthroposophic medicinal products. There is an Evaluation Department of Human Medicines that is responsible for authorisation of human medicinal products. Therefore, SAM is not able to specify the number of staff.
- **Netherlands**: The Department for the Assessment of Botanicals & Novel Foods at the Dutch Agency is responsible for the assessment of homeopathic medicinal products and herbal medicinal products and the safety assessment of novel foods (according to the European Regulation for Novel Foods).
- **Switzerland:** Eight people (four in Case Management, two in Quality assessment, one in Preclinical assessment and one in Clinical assessment), most of them have additional tasks in other areas. That means: FTEs for homeopathic and anthroposophic medicinal products: 3,5 FTEs.
  Three people (together about two others) are dealing specifically (60 per cent or more of their time) with these products, the others are spending most of their time on other, especially phytotherapeutic products.

6.3 Conclusion

Key conclusions on the number of staff at Medicines Agencies dealing with homeopathic and anthroposophic medicinal products.

- Many medicine agencies do not have specific departments dealing with homeopathic and anthroposophic medicinal products or do not have staff dedicated to this type of medicinal products. Responsibilities are often not segregated between dealing with this type of medicinal products and other types of products. As a consequence, it is difficult to assess the exact number of FTE involved in dealing with the homeopathic and anthroposophic medicinal products.

Annex A: Questionnaire

Survey on Homeopathic and Anthroposophic Medicinal Products

1. General questions

1. What is your name?
2. What is your function (i.e. position or job title)?
3. What is your e-mail address?
4. What is your phone number (in case we need to contact you for further clarification on your answers)?
5. For which country are you completing this survey?

2. Homeopathic medicinal products

6. Do you know the estimated number of finished *homeopathic medicinal products – for single or complex remedies – on the market in your country (*whatever the status may be: registered, authorised, notified or grandfathered products and others)?
   - ○ NO
   - ○ If YES, please specify

7. For the finished homeopathic medicinal products, can you provide the estimated number of products for single remedies?
   - ○ NO
   - ○ If YES, please specify

8. For the finished homeopathic medicinal products, can you provide the estimated number of products for complex remedies?
   - ○ NO
   - ○ If YES, please specify

9. Do you have any additional comments?

3. Anthroposophic medicinal products

10. Do you know the estimated number of finished *anthroposophic medicinal products – for single or complex remedies – on the market in your country (*whatever the status may be: registered, authorised, notified or grandfathered products and others)?
    - NO
    - If YES, please specify

11. For the finished anthroposophic products, can you provide the estimated number of products for single remedies?
    - NO
    - If YES, please specify

12. For the finished anthroposophic products, can you provide the estimated number of products for complex remedies?
    - NO
    - If YES, please specify

13. Do you have any additional comments?
    - NO
    - If YES, please specify

4. Notification & Registration

14. Do you know the number of notifications – for simple or complex remedies – at the Medicines Agency?
    - NO
    - If YES, please specify

15. Does this notification list make a distinction between homeopathic medicinal products subject to Art. 14 – Registration and homeopathic medicinal products subject to Art. 16 – National Marketing Authorisation?
    - NO
    - If YES, please specify

16. Do you know the year of notification or any other “preliminary transition listing” procedure?
    - NO
    - If YES, please specify

17. Are the lists of these notifications available?
    - YES
    - NO

18. Do you have any additional comments?

19. Are there products for which, in accordance with Art. 14 of Directive 2001/83/EC, either a registration has been granted or the process of assessment for a registration has been started?
    - NO
    - If YES, please specify

20. Do you have any additional comments?

21. In accordance with Article 14: do you know the number of products granted a registration?
- NO
- If YES, please specify

22. In accordance with Article 14: do you know the number of applications under assessment?
- NO
- If YES, please specify

23. Are lists of these products published or available?
- YES
- NO

24. Do you have any additional comments?

25. Has a specific legal category been provided in accordance with Art. 16.2 of Directive 2001/83/EC?
- YES
- NO

26. Do you have any additional comments?

27. Are there products for which, in accordance with Art. 16.2 of Directive 2001/83/EC, either a national marketing authorisation has been granted or the process of assessment for a national marketing authorisation has been started?
- NO
- If YES, please specify

28. In accordance with Article 16.2: Do you know the number of products that have been granted a national marketing authorisation?
- NO
- If YES, please specify

29. In accordance with Article 16.2: Do you know the number of applications under assessment?
- NO
- If YES, please specify

30. Are lists of these products published or otherwise available?
- YES
- NO

31. Do you have any additional comments?

32. Do you know in how many mutual recognition procedures (Mutual Recognition Procedure or De-centralised Procedure) for homeopathic medicinal products registered in accordance with Article 14 your country has participated as a reference Member State?
- NO
- If YES, please specify

33. Do you know in how many mutual recognition procedures (Mutual Recognition Procedure or De-centralised Procedure) for homeopathic medicinal products registered in accordance with Article 14 your country has participated as a concerned Member State?
- NO
- If YES, please specify

34. Do you have any additional comments?

5. The Medicines Agency in the different EU Member States

35. Do you know the number of staff (in FTEs) occupied in the department responsible for homeopathic and anthroposophic medicinal products in your country for the Medicines Agency?
- NO
- If YES, please specify

36. Do you know the percentage within this number that is specifically dealing with homeopathic and anthroposophic medicinal products?
- NO
- If YES, please specify

37. Do you have any additional comments?

Annex B: Glossary

Abbreviations

- AMM: Authorisation de Mise sur le Marché
- CAM: Complementary and Alternative Medicines
- ECHAMP: European Coalition on Homeopathic and Anthroposophic Medicinal Products
- EDQM: European Directorate for the Quality of Medicines & HealthCare
- EEA: The European Economic Area. At present, the contracting parties to the EEA Agreement are the EU and its 27 members plus Iceland, Liechtenstein and Norway.
- EMEA: European Medicines Agency
- FAGG-AFMPS: Federal Agency for Medicines and Health Products in Belgium
- FTE: fulltime-equivalent
- HAMP: Homeopathic and Anthroposophic Medicinal Products
- HCG: Homeopathic medicinal products for human and veterinary use
- HMA: Heads of Medicines Agencies
- HMP: Homeopathic Medicinal Product
- HMPSR: Homeopathic Medicinal Product for Single Remedies
- HoA: Working Group for Homeopathic Medicinal Products
- IAAP: International Association of Anthroposophic Pharmacists
- MEB: Medicines Evaluation Board
- MHRA: Medicines and Healthcare products Regulatory Agency
- MRP: Mutual Recognition Procedure
- PLR: Product License of Rights
- SAM: State Agency of Medicines (Latvia)

Definitions:

- **Allopathic medicine**[90] focuses on treating specific symptoms in isolation, rather than considering the whole patient.
- **Alternative medicine**[91] is used instead of conventional medicine. An example of an alternative therapy is using a special diet to treat cancer instead of undergoing surgery, radiation, or chemotherapy.
- **Ayurvedic medicine**[92] is an alternative medical practice that claims it is based on the traditional medicine of India. Western medicine has ayurveda classified as a system of complementary and alternative medicine (CAM) that is used to complement, rather than replace.
- **Complementary medicine**[93]: a group of diagnostic and therapeutic disciplines that are used together with conventional medicine. An example of a complementary therapy is aromatherapy to reduce a patient's discomfort following surgery.
- **Complex remedy**[94]**:** a system of homeopathic medicine that has more than one remedy combined together in one dosage form.

[90] http://www.ottawaeft.com/health-resources/allopathic-medicine
[91] http://www.athealth.com/consumer/disorders/cam.html
[92] http://en.wikipedia.org/wiki/Ayurveda
[93] http://www.medicinenet.com/alternative_medicine/article.htm
[94] http://medical-dictionary.thefreedictionary.com

- **Dilution**[95]: Reducing the concentration of a chemical. There are different principles of dilution in homeopathy:
    1) Hahnemann's centesimal dilution, where an active principle is diluted in 99 times its own volume of liquid, is potentiated to obtain a solution with a potency of 1CH. A drop of this solution is taken and diluted in 99 times its own volume of liquid and shaken: producing a solution with a potency of 2CH, and so on.
    2) Hahnemann's decimal dilution, where the active principle is diluted in 9 times its own volume of liquid, follows the same process, providing titrated solutions in DH.
    3) Korsakov's dilution: the process is the same, except that a single flask is used for the preparation. Instead of taking a hundredth of the solution obtained at 1CH, 99 per cent is discarded and the remaining 1 per cent diluted. At each new stage traces of the previous dilutions remain.

- **Finished homeopathic medicinal product**[96] is a homeopathic medicinal product manufactured according to industrial methods with a view to being placed on the market.
- **Grandfathered products**[97]**:** A product that is grandfathered is one that has been granted marketing authorization because it was already being marketed at the time the marketing authorization system was established.
- **Marketing authorization**[98]**:** Authorization issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation of safety, efficacy and quality. Once a product has been given marketing authorization, it is included on a list of authorized products - the register - and is often said to be "registered" or to "have registration".
- **Notification:** A product that is registered in one of the EU Member States can be marketed in any other part of the Community by a distributor ("parallel distributor") independent of the Marketing Authorisation Holder. At least 3 months prior to commencing distribution of a specific product, the parallel distributor sends the complete information (notification form) to the EMEA. When there are no objections or when objections have been completely addressed, the EMEA sends a notice to the parallel distributor, the Member State of destination and the Marketing Authorisation Holder of the medicinal product, indicating that the regulatory check has been completed. As of that moment, the medicinal product has been notified and can be distributed in the market.
- **Ordinance**: a law, a statute, a decree
- **Pharmacovigilance**[99] is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.
- **Phytotherapy**[100]**:** a type of medicine that make herbs an integral part of the treatment. In the phytotherapeutic type of medicine those herbs work in a manner that is somewhat similar to that of the pharmaceutical drugs used in conventional medicine.
- **Registration:** Once a medicinal product is registered in one of the EU Member States, the producer gained market access for this product in the entire EU market.

- **Simplified registration procedure for HAMP**[101]**:** In 1992 Directive 92/73/EC introduced a simplified registration procedure. It is regarded as simplified because although the safety and quality of products has to be demonstrated, products are not permitted to make medical claims. The simplified registration is restricted to products for oral and external use and does not allow indications (the descriptions of diseases or conditions for which the medicine is intended to be used). In order to qualify for registration the products must:
    - be for oral or external use
    - be sufficiently diluted to guarantee their safety
    - make no therapeutic claims.

[95] http://scienceofhomeopathy.blogspot.com/2009/03/principles-of-dilutions.html
[96] http://www.almp.hr/?ln=en&w=lijekovi
[97] http://www.worldpharmaceuticals.net/glossary.htm
[98] http://www.worldpharmaceuticals.net/glossary.htm
[99] The Importance of Pharmacovigilance, WHO 2002
[100] http://www.vodou.org/phytomedical.htm
[101] http://www.mhra.gov.uk/Howweregulate/Medicines/Homeopathicmedicines/index.htm

- **Single remedy**[102]**:** only one remedy at a time is prescribed to the patient. It is a form of homeopathy in which the remedy consists of highly diluted animal, drug, plant, or mineral substance that most closely matches the essence of the malady and the totality of symptoms.

[102] http://www.xs4all.nl/~healings/SingleRem.html & http://medical-dictionary.thefreedictionary.com

Annex C: Links to Medical Agencies' Sites with information on registration of homeopathic and anthroposophic medicinal products

	Health Ministries	Medical Agencies	List of registered products	Web pages with info on homeopathic products
Austria	http://www.bmgf.gv.at/	http://www.ages.at/	http://www.basg.at/news-center/statistiken/arzneimittel-in-oesterreich/	http://www.basg.at/index.php?id=295
Belgium	http://www.health.fgov.be/	http://www.fagg-afmps.be/	Under construction: http://www.fagg-afmps.be/en/items/database/index.jsp	http://www.fagg-afmps.be/en/human_use/medicines/homeopathic_medicines/
Bulgaria	http://www.mh.government.bg/	http://www.bda.bg/	http://www.bda.bg/images/stories/documents/med_inf/OTC.pdf	
Cyprus	http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument	http://www.moh.gov.cy/moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument		
Czech Rep.	http://www.mzcr.cz/	http://www.sukl.cz/	http://www.sukl.eu/modules/medication/search.php?data%5Bsearch_for%5D=&data%5Bcode%5D=&data%5Batc_group%5D=V12&data%5Bmaterial%5D=&data%5Bpath%5D=&data%5Breg%5D=&data%5Bradio%5D=none&data%5Brc%5D=&data%5Bwith_adv%5D=0&data%5Blisting%5D=100&search=Search&page=1	http://www.sukl.eu/sukl/ust-29-version-7?highlightWords=Homeopathic
Denmark	http://www.im.dk/	http://www.laegemiddelstyrelsen.dk/	http://laegemiddelstyrelsen.dk/ftp-upload/ListeOverGodkendteLaegemidler.xls (only chemical)	http://laegemiddelstyrelsen.dk/en/service-menu/search?q=Homeopathic
Estonia	http://www.sm.ee/	http://www.sam.ee/	http://193.40.10.165/register/register.php?lk=1&otsi=J&keel=eng&inim_vet=inim&raviminimi=&ta_inglise=&atc=T01RS02&mlhoidja=&spckp_algus=&spckp_lopp=&pilkp_algus=&pilkp_lopp=&mlnr=&mlkp_algus=&mlkp_lopp=	

Finland	http://www.stm.fi/	http://www.fimea.fi/	Information about Decision of the Finnish Medicines Agency on the medicinal products list will enter in to force on 1 January 2010. http://www.fimea.fi/whats_new/1/0/decision_of_the_finnish_medicines_agency_on_the_medicinal_products_list_will_enter_into_force_on_1_j	http://www.fimea.fi/license_holders/herbal_remedies/homeopathic_and_anthroposophic_preparations
France The List of the	http://www.sante.gouv.fr/	http://www.afssaps.fr/	The List of the “1163” products http://www.afssaps.fr/Activites/Pharmacopee/Que-trouver-dans-la-Pharmacopee-francaise/La-liste-des-monographies-francaises/Liste-des-souches-PPH-index-nom-homeopathique-nom-anglais/(language)/fre-FR The list of complex remedies http://www.afssaps.fr/var/afssaps_site/storage/original/application/23fb12ac319e15055f17df23bd41ae7d.pdf	The list of simplified registration is under construction
Germany	http://www.bmg.bund.de/	http://www.bfarm.de/	http://www.bfarm.de/cln_103/DE/Arzneimittel/2_zulassung/zulArten/besTherap/allgemein/statistik-bescheidzahlen.html?nn=1009778	http://www.bfarm.de/DE/Arzneimittel/2_zulassung/zulArten/besTherap/amAnthropo/amanthropo-inhalt.html;jsessionid=B1D1B104E33143A13C923AB8156B6F66.1_cid103 and http://www.bfarm.de/DE/Arzneimittel/2_zulassung/verfahren/azBuch/20azBuchKomm/20-70homoeopathAzBuchKomm/hab-Kom-inhalt.html?nn=1013988
Greece	http://www.yyka.gov.gr/	http://www.eof.gr/		
Hungary	http://www.eum.hu/	http://www.ogyi.hu/	http://www.ogyi.hu/drug_database/index.php?action=process&freetext=&product_name=0&marketing_authorisation=776&active_substance=0&atc_code=&registration_number=&dic_prescription=0&authorisation_date_from=&authorisation_date_to=&revoke_date_from=&revoke_date_to=&ordering=name_str	http://www.ogyi.hu/search/index.php?searchPhrase=Homeopathic

Ireland	http://www.dohc.ie/	http://www.imb.ie/	http://www.imb.ie/images/uploaded/swedocuments/latestHMlist.pdf	http://www.imb.ie/search.aspx?q=Homeopathic
Italy	http://www.ministerosalute.it/	http://www.agenziafarmaco.it/		http://www.agenziafarmaco.gov.it/en/glossary/term/3676 and http://www.agenziafarmaco.gov.it/en/content/registration
Latvia	http://www.vm.gov.lv/	http://www.vza.gov.lv/	List of registered products is available on print/cd version only http://www.vza.gov.lv/index.php?id=390&sa=390&top=298	
Lithuania	http://www.sam.lt/	http://www.vvkt.lt/		http://www.vvkt.lt/index.php?393335985
Luxembourg	http://www.ms.public.lu/fr/index.html	http://www.ms.public.lu/fr/activites/pharmacie-medicament/index.html		
Malta	https://ehealth.gov.mt/HealthPortal/default.aspx	http://www.medicinesauthority.gov.mt/	http://www.maltamedicineslist.com/ http://www.medicinesauthority.gov.mt/pub/MA%20List.pdf http://www.medicinesauthority.gov.mt/pub/QL%20List.pdf	http://www.medicinesauthority.gov.mt/homeopath.htm
Netherlands	http://www.rijksoverheid.nl/	http://www.cbg-meb.nl/	http://www.cbg-meb.nl/NR/rdonlyres/5CC62EF9-F610-4520-8368-2A7D200DA4F1/0/Lijst_homeopathische_farmaceutische_producten2010.pdf	http://www.cbg-meb.nl/CBG/nl/_search/SplitScreen/default.htm?qry=Homeopathy&language=nl
Poland	http://www.mz.gov.pl/	http://www.urpl.gov.pl/	http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/urzedwpl_2009_czesc_1a_16062009.pdf	
Portugal	http://www.min-saude.pt/	http://www.infarmed.pt/	http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AUTORIZACAO_DE_INTRODUCAO_NO_MERCADO/PRODUTOS_FARMACEUTICOS_HOMEOPATICOS/PFH_REGISTADOS	http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AUTORIZACAO_DE_INTRODUCAO_NO_MERCADO/PRODUTOS_FARMACEUTICOS_HOMEOPATICOS/Guidance_module3.pdf and http://www.infarmed.pt/portal/page/portal/INFARMED/PESQUISA/RESULTADOS_DA_PESQUISA

Romania	http://www.ms.ro/	http://www.anm.ro/	http://www.anm.ro/app/nom1/anm_list.asp DCI code for research: HOMEOPATE	http://www.anm.ro/focus/search.asp?zoom_query=Homeopathic&zoom_per_page=10&zoom_and=0&zoom_sort=0
Slovak Rep.	http://www.health.gov.sk/	http://www.sukl.sk/	http://www.sukl.sk/en/servis/search/searching-on-the-database-of-medicinal-products ATC code for research: V12	
Slovenia	http://www.mz.gov.si/	http://www.jazmp.si/		Access to database after free registration: http://www.jazmp.si/objave/eng/BPZ_eng.pdf In Slovenian only
Spain	http://www.msc.es/	http://www.agemed.es/		http://www.aemps.es/actividad/legislacion/espana/docs/RD1344_2007-ingles.pdf and http://www.aemps.es/actividad/documentos/tasas/docs/tasasNoResid-ingles-dic06.pdf
Sweden	http://www.sweden.gov.se/sb/d/2061	http://www.lakemedelsverket.se/	*sorted after product name*: http://www.lakemedelsverket.se/upload/halso-och-sjukvard/homeopatika/gk_homreglista%20produktnamn.pdf *Authorised (=free listed, notified) homeopathic products – sorted after product name*: http://www.lakemedelsverket.se/upload/halso-och-sjukvard/homeopatika/gk_homfrilistadlista%20produktnamn.pdf	http://www.lakemedelsverket.se/malgrupp/Foretag/Homeopatiska-lakemedel/ and http://www.lakemedelsverket.se/english/product/Homeopathic-products/
United Kingdom	http://www.dh.gov.uk/	http://www.mhra.gov.uk/		http://www.mhra.gov.uk/SearchHelp/Search/Searchresults/index.htm?within=Yes&keywords=Homeopathic