

Annex III.1: Survey on the Availability of Homeopathic and Anthroposophic Medicinal Products in five Member States of the EU

Background to the Survey



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

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1. Purpose of the Survey

The data on socio-economic, sales and demand figures presented in Chapter 2 and Annex I are complemented by a survey on the availability of homeopathic and anthroposophic medicinal products (HAMPs) in certain sample Member States, 'Assessment of the 'Availability' and 'Freedom of Choice' for HAMPs in the EU', PwC April 2012 (Annex III.2). The survey was carried out independent of industry. Its purpose is to illustrate the availability of HAMPs in countries with different regulatory situations: both regulatory environments which function for HAMPs and regulatory environments which can be considered less well-functioning.

2. Defining the Targets of the Survey

In order to generate a meaningful picture of the availability of HAMPs, it was necessary to select sample markets, and to identify test medicinal products for the survey. Since the very specific knowledge about the situation of HAMPs, a highly specific niche of the EU pharmaceutical market, is not in the public domain, yet at the same time, a lot of data is available to ECHAMP, the criteria for selection, and the selection of both the sample countries and the test medicinal products for the survey were proposed to PwC by ECHAMP, as described below.

3. Selection of Member States

The in-depth analysis of Chapter 2, Socio-Economic, Demand and Sales Data, and the data presented in Annex I of the report enabled the narrowing down and selection of markets. The selection of Member States allows the results of the survey to supplement the data in a way which is meaningful for the European situation. Thus in the survey, the availability of HAMPs in two Member States of doubtlessly functioning regulatory environment (defining a certain standard of availability) is compared with that of three Member States where the regulatory environment is less favourable.

In selecting the sample countries for the survey, the following general pre-conditions were applied:

- the size of the population should be representative
- a demand for homeopathic medicinal products should be visible
- the countries chosen should represent different regulatory situations of HAMPs.

3.1 Member States in a functioning regulatory environment

The first aim was to define Member States with a well-functioning regulatory environment for HAMPs, in order to be able to set a benchmark of availability with which the situation of other countries can be compared.

The standard situation was defined as follows:

- Article 16.2 of Directive 2001/83/EC has been implemented
- there are legal and regulatory solutions for the provision of homeopathic medicinal products in small batches by industry still guaranteeing the quality of the products
- the national medicines agencies are equipped with specific teams responsible for the evaluation of HAMPs
- the re-registration of HAMPs (implementing Directive 92/73/EC) is concluded, or, alternatively, the re-registration is progressing with an official time table in place, while official transition regulations are in work until final registrations are in place
- new submissions are being evaluated.

France and Germany meet these criteria. In addition they also both:

- represent the major (in fact the biggest) Member States of the EU (with respect to population and Gross National Product), which means unbiased buying power for medicinal products
- are Western EU countries of the EU 15 (pre-2004), thus the first homeopathic Directive 92/73/EC was implemented in the early nineties
- are characterised by a considerable order of magnitude with respect to the total pharma market, demonstrating that there is a certain buying power for medicinal products in general. At the same time, the figures (sales of homeopathic medicinal products per inhabitant as well as homeopathic prescribers per 100,000 inhabitants) indicate considerable demand for HAMPs.

Thus were France and Germany selected as sample Member States with a functioning regulatory environment.

3.2 Member States with a less favourable regulatory environment

The following scenarios were compared to the standard situation.

Firstly, another major Western European market where Directive 92/73/EC should have been implemented in the early nineties; the regulatory environment is characterised as follows:

- homeopathic medicinal products are still brought into the market under transition regulations
- as at the end of 2011, there are no officially issued registrations or marketing authorisations.

Spain was selected for the following considerations:

- Article 16.2 of the Directive has been implemented at a legal level, and this type of product exists on the market under transition law
- The market for homeopathic medicinal products compared to the total pharma market is still considerable. There is also a visible demand for HAMPs as demonstrated by key figures: the number of homeopathic prescribers per inhabitant is in the same range as in Germany and France, while the sales per inhabitant are smaller than in the standard countries but still relevant.

Secondly, two samples of Eastern European State were defined, where Directive 2001/83/EC with its regulations for homeopathic medicinal products has been recently implemented (mid 2000s). Both situations are characterised by a comparatively short history of official regulation of homeopathic medicinal products.

The first scenario was characterised by the following regulatory environment:

- Article 16.2 of the Directive has been implemented
- Industry is experiencing a well-functioning regulatory system today, characterised by the fact that submissions are currently being evaluated.

Bulgaria was selected for the following reasons:

- A comparatively high number of homeopathic prescribers per thousand inhabitants is considered a guarantee of a certain demand for homeopathic medicinal products.

The second scenario was characterised by the following regulatory environment:

- Article 16.2 of the Directive has not been implemented
- Although some simplified registrations are indicated on the agency website, the activity of the agency is not perceived as functioning by industry with respect to the progress of submissions.

Romania was selected for the following reasons:

- While the level of sales of homeopathic medicinal products per inhabitant is low, there are a significant number of homeopathic prescribers, which is seen as an indication for a demand in homeopathic medicinal products.

3.3 Selected Member States

In summary, the following regulatory situations were tested in the survey:

- 'Old Western European' Member States with a functioning regulatory system: examples France and Germany
- 'Old Western European' Member State with a non-functioning regulatory system : example Spain,
- 'New Eastern European' Member State with currently working regulatory procedures but short regulatory history: example Bulgaria
- 'New Eastern European' Member State with a short regulatory history where regulatory progress currently is not reported: example Romania.

4. Selection of Medicinal Products

4.1 Basic principles

The following principles and considerations were applied in the selection of medicinal products for the survey:

- A set of four medicinal products were defined in order to examine the availability of homeopathic medicinal products (according to the definition of Article 1.5 of Directive 2001/83/EC) used in homeopathy:
 - two medicinal products with no therapeutic indication reflecting the 'classical' single remedy homeopathy with its individual approach; they are expected to be available based on a regulatory scheme in accordance with the provisions of Articles 14 and 15 of Directive 2001/83/EC
 - two medicinal products with a therapeutic indication, simulating homeopathic 'speciality' product lines; they are expected to be available based on a regulatory scheme in accordance with the provisions of Article 16.2 of Directive 2001/83/EC, if relevant.
- Two additional products were defined in order to test the availability of anthroposophic medicinal products falling under the definition of homeopathic medicinal products according to article 1.5 of Directive 2001/83/EC
- Thus were six products defined – two each of three product types. For each product type described one specification is defined to simulate a common and frequent therapeutic need (demand) (also accessible to self-medication) and one additional specification representing a more specific situation (occurring not so frequently, rather implying a therapy situation possibly involving a doctor). The product specific details are given below.
- A scenario was simulated, whereby the data collector visits the pharmacy or health food shop (as relevant, according to the specific situation as regards national distribution) without a prescription in order to ask for the medicinal products. This scenario was preferred for practical reasons because it facilitates the data collection process if there is no step involving a contact with a doctor.

- The definition of the test medicinal products was independent from individual manufacturers; this means that a 'generic' product description was given. Although market interest of manufacturers will always be one of the factors influencing availability, this measure contributes to a reduction in possible bias of the survey results caused by individual/accidental/historically grown competition situations.

4.2 Selection of medicinal products and rationale

4.2.1 Pulsatilla

Synonyms:

- Anemone pratensis, Pulsatilla nigricans, Pulsatilla pratensis
- Related remedy: Pulsatilla vulgaris

Rationale:

- Represents classical single remedy - homeopathy with individual therapeutic approach
- Generic medicinal product
- Remedy without indication
- Very common medicine frequently recommended by prescribers all over the world
- Polychrest: a homeopathic remedy with an extended material medica of symptoms which is well known and strongly confirmed by successful use
- Very important remedy for homeopathic prescribers and at the same time frequently used in self-treatment single remedy homeopathy.^{1 2 3}
- There are official pharmacopoeia monographs for Pulsatilla pratensis (German Homoeopathic Pharmacopoeia, HAB), and Pulsatilla vulgaris (French Homoeopathic Pharmacopoeia, Ph. Fr.).

4.2.2 Formica rufa

Synonyms:

- None

Rationale:

- Represents classical single remedy homeopathy with individual therapeutic approach
- Generic medicinal product
- Remedy without indication
- Remedy is broadly needed by different individual schools of homeopathy, but is more relevant to prescribers for therapy of chronic diseases:^{4 5 6 7 8} frequent application for the following conditions: Asthma, allergies, night sweats, chronic inflammations
- There are official pharmacopoeia monographs in the HAB as well as in the Ph.Fr.

¹ A.V. Schmukler: Homeopathy - An A to Z Home Handbook. Llewellyn Publications 2006, Woodbury, USA

² A. Steinsbekk et al. 2004: the use of simplified constitutional indications for self-prescription of homeopathic medicine. Complementary Therapies in Medicine 12:112-117

³ C. Witt et al 2009: Homeopathic treatment of patients with chronic sinusitis: A prospective observational study with 8 years follow-up. BMC Ear, Nose and Throat Disorders 2009, 9:7, doi:10.1186/1472-6815-9-7

⁴ Boericke W. Boericke's New Manual of Homeopathic Materia Medica with Repertory including Indian Drugs, Nosodes, Uncommon Rare Remedies, Mother Tinctures, Relationships, Sides of the Body, Drug Affinities & List of Abbreviations. 3rd edition. New Delhi (India): B. Jain Publishers (P) Ltd.; 2010

⁵ Dufilho R. Le Piano Homéopathique. 2nd edition. Paris (France): Éditions Similia; 2000

⁶ Leeser, O. Lehrbuch der Homöopathie: Spezieller Teil: Arzneimittellehre, C: Tierstoffe. 1st edition Ulm (Germany): Karl F. Haug Verlag; 1961

⁷ Vermeulen F. Concordant Materia Medica 1st edition Haarlem (The Netherlands): Merlijn Publishers; 1994

⁸ Van Zandvoort R. The Complete Materia Medica mind 1st edition Meppel (The Netherlands): Krips Repro; 1995

4.2.3 Specialty homeopathic medicinal product for common cold, 'flu or 'flu-like symptoms

Rationale:

- Homeopathic medicine requested through a therapeutic indication (homeopathic combination product)
- A direction of indication is given instead of a concrete product name which would link the medicinal products to a brand or a specific manufacturer; so, the product selection is also independent of the brand names in different countries
- OTC indication which is covered by homeopathy⁹
- Indication of high impact, frequently needed.

4.2.4 Speciality homeopathic medicinal product for stress or exhaustion

Rationale:

- Homeopathic medicine requested through a therapeutic indication (homeopathic combination product)
- A direction of indication is given instead of a concrete product name which would link the medicinal products to a brand or a specific manufacturer; so, the product selection is also independent of the brand names in different countries
- It has an OTC indication which is covered by homeopathy¹⁰ but the indication is also relevant for doctors
- A more limited impact and less frequently needed, but still representative indication
- A condition for which the interviewer does not risk being sent to the doctor by the pharmacist.

4.2.5 Anthroposophic medicinal product based on preparations of Gold (Aurum), Stibium (Antimon) and Hyoscyamus, to calm down stress at work resulting in sleeping disorders and anxiety

Existing alternatives:

- (i) Aurum/Stibium/Hyoscyamus, Globuli (Wala Heilmittel GmbH)
- (ii) Aurum/Hyoscyamus comp., liquid dilution (Weleda AG)

Rationale:

- Relevant 'modern' indication, much needed medicine
- Medicine offered by the two main manufacturers of anthroposophic medicinal products in the EU
- Generic medicines: production by homeopathic methods, effectiveness Commission C monograph 'Aurum/ Hyoscyamus comp'¹¹
- Specific for anthroposophic medicine
- Medicines described in the Vademecum;¹² the names of the manufacturers were given in order to make it easier for the pharmacist to find the product.

⁹ MHRA - The Homeopathic National Rules Scheme, The Medicines and Healthcare Products Regulatory Agency (MHRA); 2006, Available from: <http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con2024923.pdf> [Quoted 07.12.2011]

¹⁰ MHRA 2006 as above

¹¹ Commission C, Monographs - Aurum/Hyoscyamus comp., publication in Federal Gazette (Bundesanzeiger) n°65a, 07.04.1988

4.2.6 Anthroposophic medicinal product, an ointment based on mercurialis for badly healing wounds

Existing alternatives:

- (i) Mercurialis perennis 10% Salbe (ointment), (Weleda AG)
- (ii) Mercurialis Salbe (ointment) (Wala Heilmittel GmbH)

Rationale:

- Relevant indication for self-medication, that could also be endorsed by a doctor
- Medicine offered by the two main manufacturers of anthroposophic medical products in the EU
- Generic medicines: production by homeopathic methods, effectiveness Commission C monographs 'Mercurialis perennis' and 'Allium cepa/ Mercurialis comp.'¹³
- Specificity for anthroposophic medicine: as ointment Mercurialis is used in anthroposophic medicine only; no ointment of other companies available
- Medicines described in high level OTC literature;^{14 15} the names of the manufacturers were given in order to make it easier for the pharmacist to find the product.

¹² Vademecum Anthroposophische Arzneimittel, First edition 2008 by 'Gesellschaft Anthroposophischer Ärzte in Deutschland' and 'Medizinische Sektion der Freien Hochschule für Geisteswissenschaft Dornach/Schweiz'

¹³ Commission C, Monographs - Mercurialis perennis, publication in Federal Gazette (Bundesanzeiger) n° 43a, 02.03.1991; Allium cepa/Mercurialis comp., publication in Federal Gazette (Bundesanzeiger) n° 43a, 02.03.1991

¹⁴ Michaela Glöckler, Heide Tetzner, Birgit Emde: 'Selbstmedikation' in: Anthroposophische Arzneitherapie. 1. Ausgabe, Stuttgart: Wissenschaftliche Verlagsgesellschaft; 2010

¹⁵ Gesellschaft Anthroposophischer Ärzte in Deutschland, Medizinische Sektion der Freien Hochschule für Geisteswissenschaft Dornach/Schweiz: Vademecum Anthroposophische Arzneimittel. 1. edition, Gesellschaft Anthroposophischer Ärzte in Deutschland, Roggenstrasse 82, D-70794 Filderstadt, 2008