

## **TRANSPARENCY COMMITTEE**

### **EVIDENCE FOR HOMEOPATHIC MEDICINES SUBJECT TO THE REGISTRATION PROCEDURE PROVIDED FOR ARTICLE L.5121-13 OF THE FRENCH CODE OF PUBLIC HEALTH**

*This document is an English summary of the assessment and appraisal document of homeopathic medicines published on 26 June 2019.*

*The complete and legally binding document "[Commission de la Transparence Evaluation des médicaments homéopathiques soumis à la procédure d'enregistrement prévue à l'article L.5121-13 du CSP](#)" is available in French on the HAS website*

## TABLE OF CONTENTS

|  |           |
|--|-----------|
| <b>ABBREVIATIONS</b> .....   | <b>3</b>  |
| <b>01 BACKGROUND</b> .....   | <b>4</b>  |
| <b>02 DATA IDENTIFICATION AND SELECTION METHODS</b> .....                | <b>6</b>  |
| <b>02.1 DATA FROM SYSTEMATIC LITERATURE REVIEW</b> .....                 | <b>6</b>  |
| 2.1.1 <i>Efficacy and safety</i> .....                                   | <b>6</b>  |
| 2.1.2 <i>Other criteria of public health benefit</i> .....               | <b>8</b>  |
| <b>02.2 DATA FROM STAKEHOLDERS</b> .....                                 | <b>9</b>  |
| 2.2.1 <i>Pharmaceutical companies</i> .....                              | <b>9</b>  |
| 2.2.2 <i>Other stakeholders</i> .....                                    | <b>9</b>  |
| <b>03 RESULTS SUMMARY</b> .....  | <b>11</b> |
| <b>04 DISCUSSION</b> .....   | <b>14</b> |
| <b>05 COMMITTEE'S CONCLUSIONS</b> .....                                  | <b>15</b> |
| <b>APPENDIX 1: DOCUMENTARY SEARCH STRATEGY</b> .....                     | <b>16</b> |
| <b>APPENDIX 2: SLR/MA PRISMA FLOW DIAGRAM</b> .....                      | <b>19</b> |
| <b>APPENDIX 3: RCT PRISMA FLOW DIAGRAM</b> .....                         | <b>20</b> |
| <b>APPENDIX 4: PHB PRISMA FLOW DIAGRAM</b> .....                         | <b>21</b> |
| <b>ANNEXE 5 : TABLEAU DES ETUDES DEPOSEES PAR LES LABORATOIRES</b> ..... | <b>22</b> |
| <b>APPENDIX 6: STAKEHOLDERS SURVEY</b> .....                             | <b>25</b> |
| <b>APPENDIX 7: STUDIES SELECTED FOR THE ANALYSIS</b> .....               | <b>27</b> |
| <b>APPENDIX 8 : TABLE OF STUDIES EXCLUDED ON FULL TEXT</b> .....         | <b>28</b> |
| <b>LISTE DES RÉFÉRENCES</b> .....  | <b>34</b> |

## ABBREVIATIONS

|         |  |
|---------|--|
| CH      | Centésimales hahnemaniennes (Hahnemann's centesimals)  |
| CSP     | Code de la santé publique (French public health code)  |
| GP      | General Practitioner   |
| HAS     | Haute Autorité de santé (French National Authority for Health)   |
| HTA     | Health Technology Assessment   |
| MA      | Meta-analysis  |
| NSAIDs  | Nonsteroidal anti-inflammatory drugs   |
| PHB     | Public health benefit  |
| PICOTS  | Population, intervention, control, <i>outcome</i> , <i>timeframe</i> study design                          |
| RCT     | Randomised controlled trials   |
| TC      | Commission de la transparence (Transparency Committee)   |
| SLR     | Systematic Literature Review   |
| SNIIRAM | Système national d'information inter-régimes de l'assurance maladie (French National Health Fund database) |

## ► Principles of homeopathy

Homeopathy is an alternative medicine devised in the 18th Century by the German doctor Samuel Hahnemann. It is based on several basic principles: the principle of *similitude* (“like cures like”), the principle of *ultra-dilution*, the principle of *dynamisation* (or *potentisation*) and the principle of *individualisation*. Therefore, it consists of the administration of preparations of very low and dynamised doses, prepared from mother tinctures likely to cause symptoms similar to the targeted symptoms in healthy humans.

## ► Request from the Ministry of Solidarity and Health

On 27 March 2019, the French Ministry of Health requested the French National Authority for Health (HAS) to assess the validity of maintaining the current reimbursement scheme of homeopathic medicines by the National Health Fund. The request concerned all homeopathic medicines falling under article L.5121-13 of the French public health code and eligible for reimbursement according to the September 12<sup>th</sup>, 1984 order, amended in 1989.

This assessment therefore covers common name homeopathic medicines subject to the French registration procedure and currently reimbursed up to 30%. These concern products diluted between 2 and 30CH and used by oral or external route (granules, globules, tablets, suppositories, ointment, drops etc.). Homeopathic medicines subject to marketing authorisation (examples: *Camilia*®, *Angipax*®, etc.) are not covered in this document.

The procedure and methods for assessing homeopathic medicines are laid out in articles L. 162-17-2-2 and R. 163-14-4, following the French Social Security Code. To ensure sound collective reimbursement schemes, appraisals issued by the Transparency Committee (TC) are to be based on the following:

- efficacy;
- adverse effects;
- care pathways, particularly with respect to relevant and available therapies;
- disease/condition severity;
- public health benefit (PHB).

## ► Homeopathic use in France

### Reimbursement data (1)

Data collected between 2011 and 2012 by the French National Health Fund (SNIIRAM) revealed that more than 6.7 million patients (around 10% of the population), had received at least one reimbursement for a homeopathic prescription, with a median of three reimbursements in the year. Most reimbursements were distributed to female patients (median age 45 years) with the highest proportions of reimbursements issued for children (18% of 0-4 years) and elderly patients (> 14% among the 50-80s). During this 12-month period, 118 million homeopathic medicine units were reimbursed, representing more than 18,000 different homeopathic preparations; corresponding to 55 million prescriptions, of which 2.5 million were for single homeopathic medicines.

Prescriptions were issued by more than 120,000 different prescribers (43% of prescribers in France in 2012). General practitioners (GPs) were the largest prescribing group (58%), followed by dentists (10.7%). In total, 95% of GPs, 92% of dermatologists and 93% of gynaecologists prescribed a homeopathic medicine at least once over the period studied. The most frequently reimbursed homeopathic medicines were: *Arnica montana*, *Ignatia amara* and *Influenzinum*.

## Pharmacoepidemiological study of the impact of reimbursement methods on Public Health for 3 disease groups, EPI-3 (2, 3)

EPI-3 is a French observational study conducted on a sample of GPs and their patients between March 2007 and July 2008. The objectives of this study were to provide figures on the burden of diseases most often encountered in primary medical care, to study the characteristics of prescribers and patients and to analyse GPs' prescription habits.

Sampling was conducted in two steps. GPs were first randomly selected from a national register then stratified according to their prescription preference (only conventional medicines [CM], mainly homeopathic [Ho], or mixed practice [Mx]). All patients (adults and adult-accompanied children) who consulted the selected GPs were then invited to participate in the study. Provided patient consent, all GPs were required to indicate the main reasons for patient consultation, along with prescription type (diagnostic tests, referral and treatments). Patients and the adults of accompanied children were asked to complete a self-questionnaire providing socio-demographic data (age, sex, level of education, professional status, cigarette and alcohol consumption, physical activity, weight and height), type of health insurance coverage (universal and complementary insurance) and medical history over the last 12-month consultation period (number, duration, and type of doctors consulted), hospitalisations and sick leave. Adult patients also had to fill out a quality-of-life questionnaire upon study inclusion (SF-12<sup>1</sup>) and a questionnaire about their beliefs and attitudes as to complementary and alternative medicines (CAMBI<sup>2</sup>).

In total, 825 GPs agreed to participate in the study. The mean number of patients recruited per doctor was 8.7 patients for a total of 8,559 patients. Patient average age was 43.3 years with women representing 62.7% of the study population. It was the first consultation with the participating doctor for around 10% of them, and almost half of patients (46.9%) had been consulting the GP for more than 5 years. For approximately 10% of the patients, it was a first-time consultation with the prescribing GP, with 50% having consulted the GP for more than 5 years. The main reasons for consultation were for musculoskeletal disorders (29% of consultations), followed by cardiovascular diseases (26.7%), sleep disorders, anxiety and depression (22.0%) and respiratory system disorders (19.9%).

Among the 8,559 patients having agreed to participate, 6,379 said the doctor consulted was their GP (1,691 in the CM group, 3,187 in the Mx group and 1,501 in the Ho group). Patients from the Ho group (compared to the CM group) were mainly women (63.3% *versus* 56.5%), with a higher education level (57.8% reached secondary education *versus* 40.6%), less often affected by overweight and/or obesity and with a lower rate of alcohol and tobacco consumption. Patients from the Ho group consulted less often for a cardiovascular disorder (17.4% *versus* 27.3%) but more often for a musculoskeletal disorder (14.9% *versus* 13.4%) or anxiety or depression (19.1% *versus* 15.8%). Regarding the beliefs of patients as to complementary and alternative medicines, the total CAMBI score was significantly higher in the Ho group compared to the CM group (OR = 3.43; CI<sub>95%</sub> [2.97; 3.97]) suggesting greater trust in natural and holistic treatments.

### ► Assessment and reimbursement of homeopathy in other countries (4)

In Europe, only Switzerland and Luxembourg reimburse homeopathy *via* their National Health Fund. Switzerland concluded on the efficacy of homeopathy and usefulness of its reimbursement (5, 6).

However, the Health Technology Assessment (HTA) overview conducted by Australia (7), the United Kingdom (8-11) and Belgium (12) concluded on the absence of evidence as to the efficacy of homeopathy and did not recommended reimbursement of homeopathic medicines by the National Health Fund.

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<sup>1</sup> The SF-12 score is a short version of the general SF-36 questionnaire. It contains 12 items and is used to evaluate quality-of-life physical and emotional aspects. In total, the score is between 0 and 56; the higher the score, the better the quality-of-life.

<sup>2</sup> The CAMBI (*Complementary and Alternative Medicine Beliefs Inventory*) is a three-item questionnaire (belief in natural treatments, patient treatment compliance, holistic health) adapted to CAM for evaluating trust in the treatment.

## 02 DATA IDENTIFICATION AND SELECTION METHODS

This evaluation is based on data from:

- a systematic literature review conducted by the HAS documentary department;
- a stakeholder consultation (representatives of healthcare professionals, associations of patients and users, pharmaceutical companies concerned by this assessment).

### 02.1 Data from systematic literature review

The systematic literature review was carried out according to two areas:

- the therapeutic efficacy and safety of homeopathic medicines concerned by this evaluation (i.e excluding homeopathic medicines with marketing authorisation);
- the other criteria for evaluating the PHB.

The literature search strategy is described in detail in Appendix 1. It should be noted that grey literature was also searched and literature watch was performed until April 2019.

#### 2.1.1 Efficacy and safety

Two separate searches were performed in order to identify:

- the systematic reviews, with or without meta-analysis (SLR/MA) published between 1<sup>st</sup> January 2000 and 1<sup>st</sup> January 2019, by querying the general databases (Embase, Medline, *The Cochrane Library*, Science Direct, etc.) and the databases specific to complementary and alternative medicines (CAM Quest, HOMBREX, CORE-Hom, etc.);
- and the randomised controlled trials (RCTs) having evaluated the efficacy and safety of homeopathic medicines, by querying the Medline and EMBASE databases over the same search period.

After deletion of duplicates, 881 clinical studies published between 1<sup>st</sup> January 2000 and 1<sup>st</sup> January 2019 were identified:

- 364 systematic reviews (SLR) and meta-analyses (MA);
- 517 randomised controlled trials (RCTs).

These studies were selected according to the PICOTS (Population, Intervention, Control, Outcome, Timeframe study design) defined *a priori* and described below.

#### ▸ Selection criteria

|                     |   |
|---------------------|---|
| <b>Study design</b> | <b>SLR/MA</b> <ul style="list-style-type: none"><li>▸ Systematic literature reviews with or without meta-analysis of results (SLR/MA);</li><li>▸ Aiming to identify the randomised controlled trials (RCTs) on homeopathy in a given therapeutic situation.</li></ul> <b>RCT</b> <ul style="list-style-type: none"><li>▸ RCTs, double-blind or open-label in the event of blind evaluation (except for trials evaluating quality-of-life), in a given therapeutic situation.</li></ul>  |
| <b>Population</b>   | <ul style="list-style-type: none"><li>▸ Among humans (men, women), adults or children;</li><li>▸ With a condition/symptom or treated preventively/prophylactically.</li></ul>   |
| <b>Intervention</b> | <ul style="list-style-type: none"><li>▸ Homeopathic medicines under the scope of this evaluation;</li><li>▸ Used to treat or prevent a disease or clinical symptom;</li><li>▸ Used alone or in combination with another therapy if the specific effects of the homeopathic treatments can be determined (<i>add-on studies</i>);</li><li>▸ According to all types of homeopathic practice ("standard homeopathic treatment", predefined and identical for all patients in the study, or "individualised treatment", chosen by the investigator according to the profile of each patient).</li></ul> |

|                                     |   |
|-------------------------------------|---|
| <b>Controls</b>                     | <ul style="list-style-type: none"> <li>▸ Placebo, active comparator (medicinal product or not) or no treatment.</li> </ul>  |
| <b>Outcome measures (Outcome)</b>   | <ul style="list-style-type: none"> <li>▸ Relevant and validated efficacy criteria (clinical efficacy and quality-of-life) and safety criteria (adverse effects) (defined as criteria usually taken into account by the TC in a symptom or given disease).</li> </ul>  |
| <b>Observation time (Timeframe)</b> | <ul style="list-style-type: none"> <li>▸ Relevant follow-up for the standard treatment of the symptoms or disease studied.</li> </ul>   |
| <b>Other selection criteria</b>     | <p><b><u>SLR/MA</u></b></p> <ul style="list-style-type: none"> <li>▸ MAs without prior SLR and non-systematic literature reviews were excluded;</li> <li>▸ SLR/MA not refining their search to RCTs were selected but only the results relating to the RCTs were considered;</li> <li>▸ The search period was to be longer than 10 years or otherwise substantiated;</li> <li>▸ Systematic review SLR/MA were not selected. They were used to cross reference and update the SLR/MA search;</li> <li>▸ RCT SLR/MA covering multiple diseases were not included in the analysis. These studies were used to cross reference and update the SLR/MA search;</li> <li>▸ When several SLR/MA having found the same RCTs were available, only the most recent and/or the most detailed was selected.</li> </ul> <p><b><u>RCT</u></b></p> <ul style="list-style-type: none"> <li>▸ In the pathological situations in which SLRs and MAs were selected, only the RCTs after the literature search end date for the most recent review were selected.</li> </ul> <p><b><u>SLR/MA and RCT</u></b></p> <ul style="list-style-type: none"> <li>▸ Only full articles (not including abstracts and letters to the editor) published in English or French in a scientific journal were selected for the analysis;</li> <li>▸ Only the clinical trials of which the analysis covered more than 30 patients per group were selected (except for trials conducted for diseases of symptoms with prevalence &lt; 1/2,000);</li> <li>▸ Studies having evaluated brand name homeopathic medicines with trade name (marketing authorisation) were excluded;</li> <li>▸ Studies having evaluated homeopathic medicines of which the methods of administration (parenteral, intrathecal, intraocular etc.) and of which the dilutions (&lt; 2CH and &gt; 30 CH) are outside the scope of the analysis were excluded;</li> <li>▸ Clinical guidelines and recommendations were not selected to document efficacy and safety.</li> </ul> |

## ▸ Selection results

Out of the 364 systematic reviews and meta-analyses identified, 337 were found by querying scientific databases, among which 123 were selected on the title and abstract according to the selection criteria described above. After cross-referencing, 27 articles were added to the selection for a total of 150 SLR/MA selected. After reading on the full text, 21 reviews and meta-analyses were selected for the final analysis according to the same selection criteria.

The flow diagram in Appendix 2 summarises the various stages of SLR/MA selection.

Out of the 517 randomised control clinical trials identified, 500 were found by querying scientific databases, among which 89 were selected on the title and abstract according to the set selection criteria. After cross-referencing, 17 articles were added to the selection for a total of 106 RCTs selected. After reading on the full text, 10 were selected according to the same selection criteria.

The flow diagram in RCT prisma flow summarises the various stages of RCT selection.

## 2.1.2 Other criteria of public health benefit

The literature review included a third search used to identify the other data likely to document the PHB of these medicinal products in France (impact on healthcare organisation, impact on other treatments consumption etc.). This review was conducted on French databases between 1<sup>st</sup> January 2000 and 1<sup>st</sup> January 2019.

After deletion of duplicates, 127 studies published between 1<sup>st</sup> January 2000 and 1<sup>st</sup> January 2019 were identified.

These studies were selected according to the PICOTS (Population, Intervention, Control, Outcome, Timeframe study design) defined *a priori* and described below.

### ► Selection criteria

|                                     |  |
|-------------------------------------|--|
| <b>Study design</b>                 | <ul style="list-style-type: none"> <li>▶ Any type of clinical study conducted in France* (randomised controlled trial, non-randomised controlled trial, case-control study, observational study etc.) in an identified therapeutic situation.</li> </ul>   |
| <b>Population</b>                   | <ul style="list-style-type: none"> <li>▶ In French patients (men and women, adults or children);</li> <li>▶ With a condition/symptom or treated preventively/prophylactically.</li> </ul>  |
| <b>Intervention</b>                 | <ul style="list-style-type: none"> <li>▶ Homeopathic medicines included in this evaluation;</li> <li>▶ Used to treat or prevent a disease or clinical symptom;</li> <li>▶ Used alone or in combination with another therapy if the specific effects can be determined (<i>add-on studies</i>);</li> <li>▶ According to all types of homeopathic practices.</li> </ul>  |
| <b>Controls</b>                     | <ul style="list-style-type: none"> <li>▶ Controlled (with placebo, conventional treatment or no treatment) and non-controlled study.</li> </ul>  |
| <b>Outcome measures (Outcome)</b>   | <ul style="list-style-type: none"> <li>▶ According to the relevant outcome measures used to evaluate the PHB of medicinal products (other than morbidity-mortality, safety and quality-of-life):             <ul style="list-style-type: none"> <li>• impact on organisation of care;</li> <li>• impact on prescription delay;</li> <li>• impact on healthcare consumption and the prescription of other treatments;</li> <li>• impact of potential misuse, etc.</li> </ul> </li> </ul>  |
| <b>Observation time (Timeframe)</b> | <ul style="list-style-type: none"> <li>▶ Over a relevant observation time with health population effects.</li> </ul>   |
| <b>Other selection criteria</b>     | <ul style="list-style-type: none"> <li>▶ Only the full articles (not including abstracts and letters to the editor) were selected;</li> <li>▶ Clinical guidelines and treatment recommendations were not selected;</li> <li>▶ In accordance with the assessment criteria defined for this evaluation, studies evaluating the following were not taken into account:             <ul style="list-style-type: none"> <li>• the economic and financial consequences of reimbursement or non-reimbursement of homeopathic treatment,</li> <li>• the prevalence of use of homeopathic medicines,</li> <li>• healthcare professional satisfaction with homeopathic medicines.</li> </ul> </li> </ul> |

\* Considering the prescription habits (especially for homeopathy) specific to each country, and the specific features of different healthcare systems (especially in terms of healthcare and treatment organisation), the literature search for evaluating the PHB of homeopathic medicines was refined to French studies.

### ► Selection results

Out of the 127 studies identified, 112 were found by querying databases, among which 23 were selected on the title and abstract according to the selection criteria described above. After cross-referencing, 15 articles were added to the selection for a total of 38 studies selected. After reading on the full text, 6 studies were selected for the final analysis according to the same selection criteria.

The flow diagram in Appendix 4: PHB prisma flow diagram summarises the studies selection.



## 02.2 Data from stakeholders

The stakeholders<sup>3</sup> were invited to contribute. They included:

- pharmaceutical companies marketing homeopathic medicines included in this evaluation;
- patients and users' associations;
- professional organisations and professional boards.

### 2.2.1 Pharmaceutical companies

A letter was sent to pharmaceutical companies likely to market homeopathic medicines in France on 21 November 2018 asking them to submit any data about the evaluated products. They were also asked to provide the TC with any other relevant data related to homeopathy.

Three pharmaceutical companies (Boiron, Lehning-Rocal and Weleda) were concerned by this evaluation and submitted a dossier (7 January 2019).

The data submitted by the companies were selected according to the same PICOTS criteria. Overall, no additional relevant publication was identified in these submission dossiers as compared to the literature review conducted by HAS. The list of publications submitted by the companies for evaluating the efficacy, safety and PHB of homeopathic medicines (after deletion of duplicates) is available in Appendix 5.

### 2.2.2 Other stakeholders

The stakeholder's point of view was requested through an open call on the HAS website. Then, stakeholders' opinions requiring an explanation were heard by a TC *ad hoc* subgroup.

#### ► Open call for contribution from stakeholders

The call for contributions was open on the HAS website from 13 December 2018 to 27 January 2019 inviting professional, patient and users' associations to express their points of view.

The open call for contributions was also proactively sent with 117 pre-identified organisations.

The goal of the survey was to standardise contributions and to collect written points of view on all the aspects of the evaluation, namely:

- the types of target conditions or symptoms;
- the clinical advantages and disadvantages of homeopathy, in particular with respect to the alternatives available;
- impact of homeopathy on healthcare organisation;
- the work method used and any other information considered to be useful for the TC evaluation.

The on-line survey can be found in Appendix 6.

Among the 117 stakeholders contacted by e-mail (87), post (11) or both (19), 19 asked to participate to the open call for contribution from stakeholders. Conversely, 53 organisations not initially contacted submitted a participation request.

Among the 72 (19 + 53) applicants, 42 had eligible status (professional, patient and users associations) of which 29 effectively contributed.

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<sup>3</sup> The healthcare expertise charter defines stakeholders as "people or groups affected or likely to be affected, directly or indirectly, by the consequences of the decision, especially from associations and economic stakeholders or professionals, or who represent the general interests of groups affected by the said consequences".

## ► Hearings

On 20 March 2019, 11 stakeholders, from whom the HAS required further explanation as to their written contribution, were invited to an oral hearing (Collège national des généralistes enseignants, Collège de la médecine générale, Collectif Fakemed, Fédération française des sociétés d'homéopathie, Société savante d'homéopathie, Société savante de médecine anthroposophique, Société homéopathique internationale des soins de support en oncologie, Syndicat national des médecins homéopathes français, Les entreprises du médicament [LEEM], Association homéopatiens et France assos-santé).

These stakeholders were heard on 2 April 2019 by an *ad hoc* subgroup of eight TC members (the chairman and the two vice-chairmen, a GP, a pharmacist, a dermatologist, a patient and users association's representative and a methodologist). In total, 10 stakeholders out of the 11 contacted were heard (France assos-santé could not be available on 2 April).

Stakeholders could submit literature in their written contributions and/or during the oral hearing. However, no new publications were identified in the contributions as compared to the literature review conducted by HAS according to the same PICOTS criteria.

**In total, based on the systematic literature conducted by HAS, more than one thousand studies were identified and assessed. The data selected to evaluate the efficacy, safety, PHB and the role of homeopathic medicines were taken from 21 systematic literature reviews and meta-analyses, 10 randomised controlled trials and 6 PHB studies targetting 24 health conditions.**

**The studies (SLR/MA, RCT, PHB) not selected for the analysis (i.e selected on the title and abstract but excluded on the full text) and their exclusion reasons, are listed in Appendix 7. The table in Appendix 8 lists the studies selected for this evaluation according to the target health conditions.**

## 03 RESULTS SUMMARY

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### ► Principles of homeopathy

The homeopathic theory was largely discussed among the TC members during the plenary session. Overall, they concluded that the homeopathy principles are not supported by current scientific knowledge. To date, no additional mechanism of action to that of the placebo effect has been demonstrated to be able to explain the clinical response likely to be observed with homeopathy.

### ► Clinical data analysis

More than 1,000 studies were identified and almost 300 were selected on the basis of predefined selection criteria. On the 24 health conditions targeted by the publications, 12 therapeutic areas were identified:

- analgesia and traumatology: post-operative pain, prevention of inflammation;
- dermatology: plantar warts and verrucas;
- poisoning: lead poisoning;
- gynaecology: vaginal candidiasis;
- neurology: headaches and migraines;
- respiratory and allergic: asthma, respiratory tract infections, allergic rhinitis;
- psychiatry and behavioural disorders: anxiety, depression, sleep disorders, ADHD;
- rheumatology: arthritis, rheumatoid arthritis, musculoskeletal disorders;
- oncology supportive care: management of adverse effects from cancer drugs;
- functional somatic disorders: chronic fatigue syndrome.

Additionally, the literature analysis also identified data in:

- children: especially diarrhoea, acute respiratory tract infections, otitis media, prevention of post-vaccination febrile episodes and ADHD;
- pregnancy or breastfeeding women: lactation suppression or induction of spontaneous labour.

### **Efficacy**

Efficacy and safety data were identified for 21 health conditions (from 21 literature reviews and meta-analyses and 10 randomised controlled trials):

- in 9 health conditions, the efficacy data available did not show statistically significant differences between homeopathic medicines and the placebo;
- in 4 health conditions, the efficacy data available did not show any statistically significant differences between homeopathic medicines and active comparators, which were not necessarily considered to be clinically relevant comparators (depression, vulvar-vaginal candidiasis, allergic rhinitis and acute respiratory tract infections);
- in 8 health conditions (post-operative pain, post-operative inflammation, infantile otitis, chronic fatigue syndrome, depression, headaches/migraine, induction of labour and lactation suppression), the efficacy data available sometimes showed a statistically significant difference compared to the placebo or to the comparator. However, due to methodological limits (lack of generalizability due to the small numbers in frequent clinical conditions, absence of control for some outcomes, lack of detailed statistical plan, limited clinical relevance of some endpoints or even discordant results between studies etc.) superiority of homeopathic medicines could not be concluded on the basis of these studies.

Overall, no robust studies showed the superiority of homeopathic medicines over conventional treatments or the placebo in terms of efficacy (morbidity). Additionally, no studies with evaluation of patient quality-of-life as primary objective were identified. As a result, no impact on quality-of-life was demonstrated.

## Safety

Although safety data were not reported in most of the selected evidence, the literature review did not identify serious adverse events. In conclusion, the data available show the favourable safety profile of homeopathic medicines.

## Public health benefit

Six studies in 5 health conditions were selected for the evaluation of the PHB criteria. The majority of publications were based on the French observational EPI-3 study.

The EPI-3 study's methodology is described in the "Background" chapter (see "Use of homeopathy in France" section). This study showed that the patients consulting homeopathic GPs are different from those consulting conventional GPs. They are mainly women, with a higher education level, less often affected by overweight and/or obesity and with a lower rate of alcohol and tobacco consumption. It also appears that the homeopathic GPs consulted are less often their referring GP, suggesting that homeopathy may be used as a complementary therapy or used after a previous treatment failure.

This study which described clinical practices also showed less use of NSAIDs, antibiotics and psychoactive substances among patients consulting a homeopathic GP compared to those consulting a conventional GP. No difference in terms of clinical outcome was however observed.

The Committee acknowledged the relevance of the EPI-3 study to describe healthcare practices. Although, it is interesting and logical to note that GPs practising homeopathy prescribe fewer conventional treatments than exclusively conventional GPs, the Committee considered that these data cannot be used to conclude on the benefit of homeopathic medicines on healthcare consumption. The EPI3 study was indeed designed so as to compare homeopathic medical practices to conventional medical practices. Therefore, the PHB of homeopathic medicines cannot be assessed based on these data.

Furthermore, the methodology of this observational study has major limitations:

- there are major confounding factors due to the strong correlation between the doctors' prescription preferences (exposure) and the patients' characteristics. Consequently, the link between the reduction in conventional medicinal product consumption and the exposure can not be established. Indeed, the prescription and consultation preference impact medicinal product consumption, which cannot be corrected;
- regarding the statistical analysis performed, although adjustment was performed using a propensity score on around ten variables to increase groups comparability, it is impossible to conclude on the absence of residual confounding factors given:
  - o the absence of a preliminary, rigorous and exhaustive strategy to identify the known confounding factors;
  - o the absence of graphic representation (directed acyclic graph) of the causal assumptions used to justify the appropriate selection of confounding factors;
  - o the lack of details regarding the model used to estimate the propensity score;
  - o the fact that it was not possible to conclude that the adjustment effectively improved the groups comparability in the absence of reliable diagnosis for estimation of the modelled propensity score (distribution of propensity scores in the groups);
  - o the absence of a 3-group generalised propensity score using the inverse probability weighting approach which is the most appropriate method for modelling the propensity for 3 exposure groups;
  - o and the absence of a negative control (falsification variable);
- finally, the hypothetico-deductive method of this study cannot be verified as a protocol was not prespecified. This means that these results should be considered exploratory, and that a publication bias remains possible.

In conclusion, based on the data available and especially the EPI-3 study an impact of homeopathic medicines on the reduction of consumption of other medicinal products, healthcare organisation, hospitalisations, misuse or late treatment is not demonstrated.

### ► Stakeholders' contributions

The Committee notes that one of the main arguments put forward in the contributions of the stakeholders in favour of maintaining reimbursement, was the original therapeutic method of homeopathy, focused on an individualised approach, especially through a close doctor/patient relationship. Patients and prescribed satisfaction and adherence to homeopathy were also recalled. The absence of iatrogenicity and contraindications to homeopathic medicines and therefore their possible use in fragile populations (pregnant women, elderly, children and infants etc.) were often brought up. Finally, the stakeholders in favour of maintaining reimbursement of homeopathy mentioned the risk of unequal access to care and misuse or incorrect use of homeopathic medicines in the event of non-reimbursement, whereas today it is practised by doctors, which ensures its safety of use.

*In contrast*, stakeholders not in favour of reimbursement mainly mentioned the absence of evidence of superior efficacy to placebo, the risks of late use or non-use of appropriate therapeutic or preventive treatment, and the fact that the “reimbursable status” is implicitly associated with recognition of clinical benefit. Finally, according to these stakeholders, the conscious use of a placebo by the doctor is no longer acceptable as it may go against the informed decision of patients in the choice of their treatment.

Written contributions are published in appendix of the French assessment and appraisal document on: [“Contributions écrites des parties prenantes reçues dans le cadre de l'évaluation des médicaments homéopathiques soumis a la procédure d'enregistrement prévue a l'article L.5121-13 du CSP”](#) (13).

## 04 DISCUSSION

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In light of the the available data, and the information provided by the stakeholders, the Committee considers that:

- to date, except the placebo effect, no mechanism of action has been demonstrated to explain the clinical response that may be observed with homeopathy;
- comparative double-blind clinical studies did not demonstrate superiority of the homeopathic approach compared to a placebo or active comparator treatment. Among the 21 health conditions for which randomised controlled trials (RCTs) or systematic reviews of RCTs were identified for evaluation of efficacy and safety, the results did not show any statistically significant differences compared to the study comparator in 13 health conditions. For the remaining 8 health conditions, the studies suggested an advantage over the comparator, however no robust conclusion could be drawn due to numerous methodological biases;
- the weak methodology of numerous studies available and the small numbers of patients included are surprising given the high prevalence of the targeted health conditions;
- the absence of comparative blinded studies, corresponding to the selection criteria established *a priori* for the literature review, to evaluate the quality-of-life of patients treated with homeopathy, is regrettable, especially for chronic or invalidating diseases;
- homeopathic medicines have a highly favourable safety profile and drug interaction profile (comparable to that of the placebo in the selected studies);
- the PHB studies, and especially the EPI-3 study, could not be used to conclude on the impact of homeopathic medicines on care organisation or consumption of other types of care or medicinal products (NSAIDs, analgesics, psychoactive substances, antibiotics). The EPI-3 study confirmed the differences in practices between homeopathic physicians and conventional physicians. However these differences could not be attributable to homeopathic medicines as treatment groups were not comparable and because of the correlation between the patients' characteristics and the doctors' preferences;
- no French studies on any late treatment or refusal of treatment were identified in the literature. The Committee highlights that if such late treatment/refusal of treatment exists, it could not be imputable to the homeopathic medicines themselves but to the homeopathic practice and to its potential misuse (especially when it is used as an alternative medicine for serious diseases or likely to become serious).

The possible substitution of homeopathic medicines by conventional medicines in the event of derembursment was discussed by the Committee. To date there is no French data available to document this potential effect or any other negative impact that might be caused by the delisting of homeopathic medicines.

The Committee emphasises that, in homeopathic practice, the time spent listening to the patient during the consultation could contribute to the positive effect of homeopathy described by patients and users. In that respect, the benefit of using a therapeutic medium such as a medicinal product to induce a placebo effect is not demonstrated.

The Committee reminds that homeopathy should not be used to treat serious and progressive diseases and that use of homeopathy means following prescriptions, including those for conventional medicines.

Additionally, in benign and/or spontaneously regressive diseases and/or some physiological conditions such as pregnancy, where there is no medical need for alternative medicines, the Committee considers that a pharmaceutical treatment (conventional or homeopathic) should not be systematic. In general, it recommends raising awareness to patients and prescribers as to the benefit of not taking medicines when they are not appropriate. The use of preventive or therapeutic approaches having demonstrated better effectiveness should be preferred.

Finally, the Committee specifies that the conditions of training of prescribers and the prescription and dispensing methods for homeopathic medicines do not fall within the scope of this document.

## 05 COMMITTEE'S CONCLUSIONS

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### Considering all of this information and further to debate and voting:

Considering:

- the absence of severity of certain benign, spontaneously regressive conditions or symptoms for which no medical need is identified and for which the use of medicines (including homeopathy) is not necessary;
- the absence of demonstration of efficacy (in terms of morbidity and/or quality-of-life) from homeopathic medicines in health conditions for which data was found in literature (non-significant data and/or methodological weaknesses limiting conclusions on superiority to the placebo or an active comparator or absence of comparison to clinically-relevant comparators);
- the absence of demonstration of their PHB, especially their benefit on the other medicinal products consumption;
- the absence of clearly-defined role of homeopathic medicines in the care pathway in health conditions for which data were found in literature;
- the absence of data in other health conditions (not found in literature) for which homeopathy is used in clinical practice and therefore the absence of role in these situations;

and despite:

- the severity and/or potential impact on the quality-of-life of patients of certain health conditions evaluated, for which there is a medical need for alternatives or complementary medicines;
- the very good safety profile of homeopathic medicines;

**the Committee issues a negative opinion on homeopathic medicines reimbursement by the French National Health Fund scheme of homeopathic medicines subject to the registration procedure provided in article L. 5121-13 of the French code of public health (14).**

## APPENDIX 1: DOCUMENTARY SEARCH STRATEGY

### Automated bibliographic databases

- Medline (National Library of Medicine, United States);
- Embase (Elsevier);
- CAM-quest database;
- HOMBREX;
- CORE-Hom;
- CAMLIS;
- Systematics & Homeopathy;
- The Cochrane Library (Wiley Interscience, United States);
- Science Direct (Elsevier);
- CAIRN;
- Lissa;
- HTA Database (International Network of Agencies for Health Technology Assessment).

### Database query strategy and results

| Study type / Topic / Terms used                          | Search period   | Number of references*  |
|--|---|------------------------|
| <b>Meta-analysis, systematic reviews</b>                 |   |                        |
| Stage 1  | "Homeopathy"[Mesh] OR Homeopathy OR Homeopathic OR Homeopat* OR Homoeopat*Field: Title/Abstract<br>AND<br>"Meta-Analysis as Topic"[Mesh] OR "Meta-Analysis "[Publication Type] OR "Review Literature as Topic"[Mesh] OR "Meta Analysis" OR "Systematic Review" OR "Literature Review" OR "Quantitative Review" OR "Pooled Analysis" OR Scoping Review Field: Title/Abstract   | 01/2000-11/2018<br>337 |
| <b>Randomised controlled trials by health conditions</b> |   |                        |
| Stage 2  | "Homeopathy"[Mesh] OR Homeopathy OR Homeopathic OR Homeopat* OR Homoeopat*Field: Title/Abstract<br>AND<br>"Random Allocation"[Mesh] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Randomized Controlled Trial "[Publication Type] OR random* Field: Title/Abstract   | 01/2000-02/2019<br>348 |
| AND stage 3  | "Diabetes Mellitus"[Mesh] OR "Dermatitis"[Mesh] OR "Eczema"[Mesh] OR "Skin Diseases"[Mesh] OR "Depression"[Mesh] OR "Depressive Disorder"[Mesh] OR "Depression, Postpartum"[Mesh] OR "Neoplasms"[Mesh] OR "Anxiety"[Mesh] OR "Asthma"[Mesh] OR "Dementia"[Mesh] OR "Osteoarthritis"[Mesh] OR "Eye Diseases"[Mesh] OR "Obesity"[Mesh] OR "Molluscum Contagiosum"[Mesh] OR "Migraine Disorders"[Mesh] OR "Headache Disorders, Primary"[Mesh] OR "Rheumatic Diseases"[Mesh] OR "Sleep Disorders, Intrinsic"[Mesh] OR "Sleep Initiation and Maintenance Disorders"[Mesh] OR "Attention Deficit Disorder with Hyperactivity"[Mesh] OR "Influenza, Human"[Mesh] OR "Gastroenteritis"[Mesh] OR "Fibromyalgia"[Mesh] OR "Fatigue Syndrome, Chronic"[Mesh] OR Chronic Fatigue OR "Enuresis"[Mesh] OR "Colonic Diseases"[Mesh] OR "HIV"[Mesh] OR "Respiratory Tract Infections"[Mesh] OR "Warts"[Mesh] OR "Mental Disorders"[Mesh] OR "Wounds and Injuries"[Mesh] OR "Premenstrual Syndrome"[Mesh] OR "Menopause"[Mesh] OR "Smoking Cessation"[Mesh] OR "Postpartum Period"[Mesh] OR "Uterine Hemorrhage"[Mesh] OR Postpartum Period"[Mesh] OR "Sleep Apnea Syndromes"[Mesh] OR "Snoring"[Mesh] OR "Rhinitis"[Mesh] OR "Edema"[Mesh] OR "Ecchymosis"[Mesh] OR "Otitis"[Mesh] OR "Diarrhea"[Mesh] OR "Pain"[Mesh] OR "Mental Disorders"[Mesh] OR Diabetic OR Diabetes OR Dermatit* OR Eczema* OR Skin Diseas* OR Depressive OR Depression OR Cancer OR Neoplasm* OR Anxiety OR Anxious OR Asthma OR Dement* OR Alzheimer OR Osteoarthritis OR Ophthalmol* OR Eye OR Obese OR Obesity OR Overweight OR Molluscum OR Migrain* OR Headache OR Rheumatic OR Insomnia OR Sleep Disorder* OR ADDH OR Hyperactiv* OR Influenza OR Gastroenteritis |                        |



|  |  |                 |     |
|--|--|-----------------|-----|
|  | OR Fibromyalgi* OR fatigue OR Enuresis* OR Colon OR Hiv OR "Respiratory OR Acute Infection* OR Wart* OR Injur* OR Wound* OR Trauma OR Premenstrual OR or Menopaus* OR Smoking OR or Post Partum OR Post Partum OR Sleep Apnea OR Snoring OR Rhinitis OR Edema OR Ecchymosis OR Otitis OR Diarrh* OR Pain* OR Mental OR Psychiatr*[tittle/abstract] |                 |     |
| <b>Randomised controlled trials: other health conditions</b> |  |                 |     |
| Stage 4  | Stage 2 NOT Stage 3  | 01/2000-02/2019 | 152 |
| <b>French studies PHB</b>                                    |  |                 |     |
| Stage 5  | "Homeopathy"[Mesh] OR Homeopathy OR Homeopathic OR Homeopat* OR Homoeopat*Field: Title/Abstract AND "France"[Mesh] OR France OR French [textword]  | 01/2000-02/2019 | 112 |
| <b>Total</b>   |  |                 | 949 |

\* After deletion of duplicates

Literature watch was continued on the topic until April 2019.

## ► Other searches

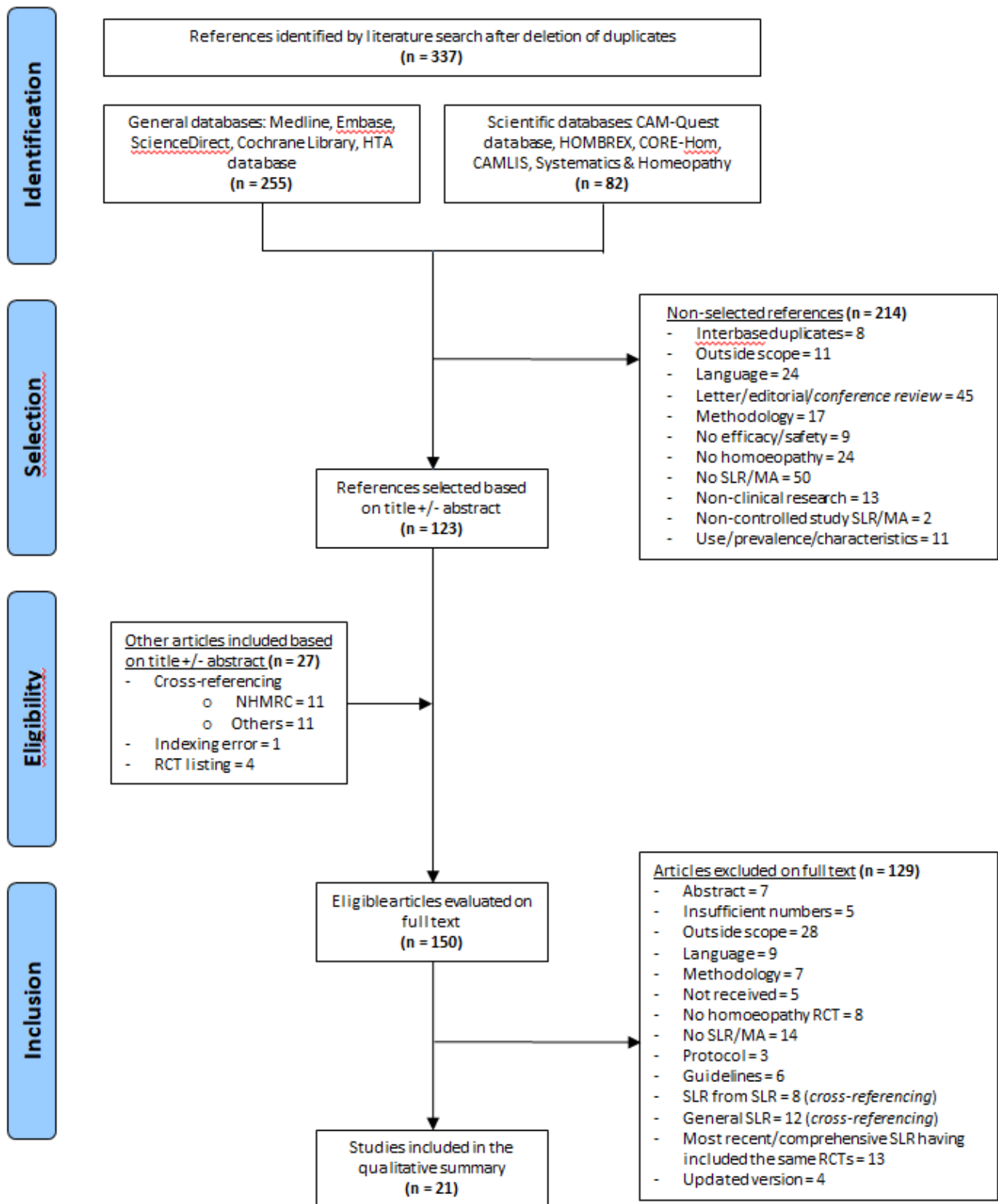
In addition, the contents of the following journals were analysed throughout the project: *Annals of Internal Medicine*, *JAMA Internal Medicine*, *British Medical Journal*, *JAMA*, *The Lancet*, *New England Journal of Medicine*, *Presse médicale*, *Homeopathy*, *Revue d'homéopathie*.

The international websites of the relevant societies cited below were searched in addition to systematically queried sources:

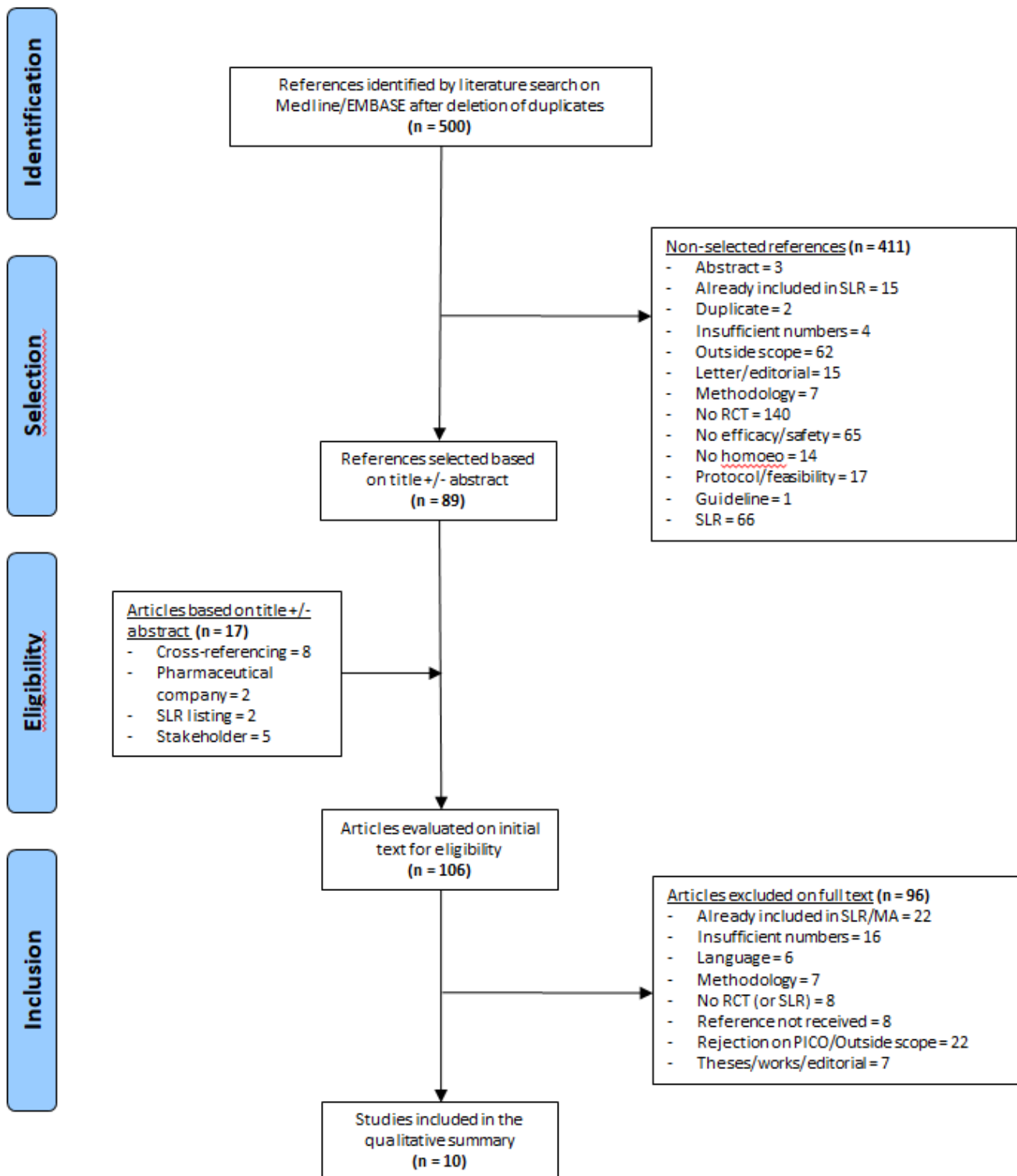
- *Adelaide Health Technology Assessment*
- *Agencia de Evaluación de Tecnología e Investigación Médicas de Cataluña*
- *Agencia de Evaluación de Tecnologías Sanitarias de Galicia*
- *Agency for Healthcare Research and Quality*
- *Alberta Heritage Foundation for Medical Research*
- *Alberta Health Services*
- *American College of Physicians*
- *American Medical Association*
- *Australian Government - Department of Health and Ageing*
- *Blue Cross Blue Shield Association - Technology Evaluation Center*
- *Bibliothèque médicale Lemanissier*
- *British Homeopathic Association*
- *Canadian Agency for Drugs and Technologies in Health*
- *California Technology Assessment Forum*
- *Centre fédéral d'expertise des soins de santé*
- *CISMeF*
- *CMAInfobase*
- *Quebec College of Physicians*
- *Cochrane Library Database*
- *Centre for Review and Dissemination databases*
- *Department of Health (UK)*
- *ECRI Institute*
- *Decision aid health technology assessment*
- *European Library for Homeopathy (Europäische Bibliothek für Homöopathie – EBH)*
- *GIN (Guidelines International Network)*

- French National Authority for Health
- *Horizon Scanning*
- *Institute for Clinical Systems Improvement*
- Institut national d'excellence en santé et en services sociaux
- Institut national de veille sanitaire
- *Instituto de Salud Carlos III / Agencia de Evaluación de Tecnologías Sanitarias*
- International Society for Complementary Medicine Research (ISCMR)
- *International Council for Homeopathy*
- *Iowa Healthcare collaborative*
- *National Coordinating Centre for Health Technology Assessment*
- *National Horizon Scanning Centre*
- *National Health and Medical Research Council*
- *National Health committee*
- *National Institute for Health and Clinical Excellence*
- *National Institutes of Health*
- National Center for Complementary and Integrative Health (NCCIH)
- *New Zealand Guidelines Group*
- *Ontario Health Technology Advisory Committee*
- Scientific Society for Homeopathy (*Wissenschaftliche Gesellschaft für Homöopathie – WissHom*)
- *Scottish Intercollegiate Guidelines Network*
- Société savante d'homéopathie
- *West Midlands Health Technology Assessment Collaboration*
- *World Health Organization*

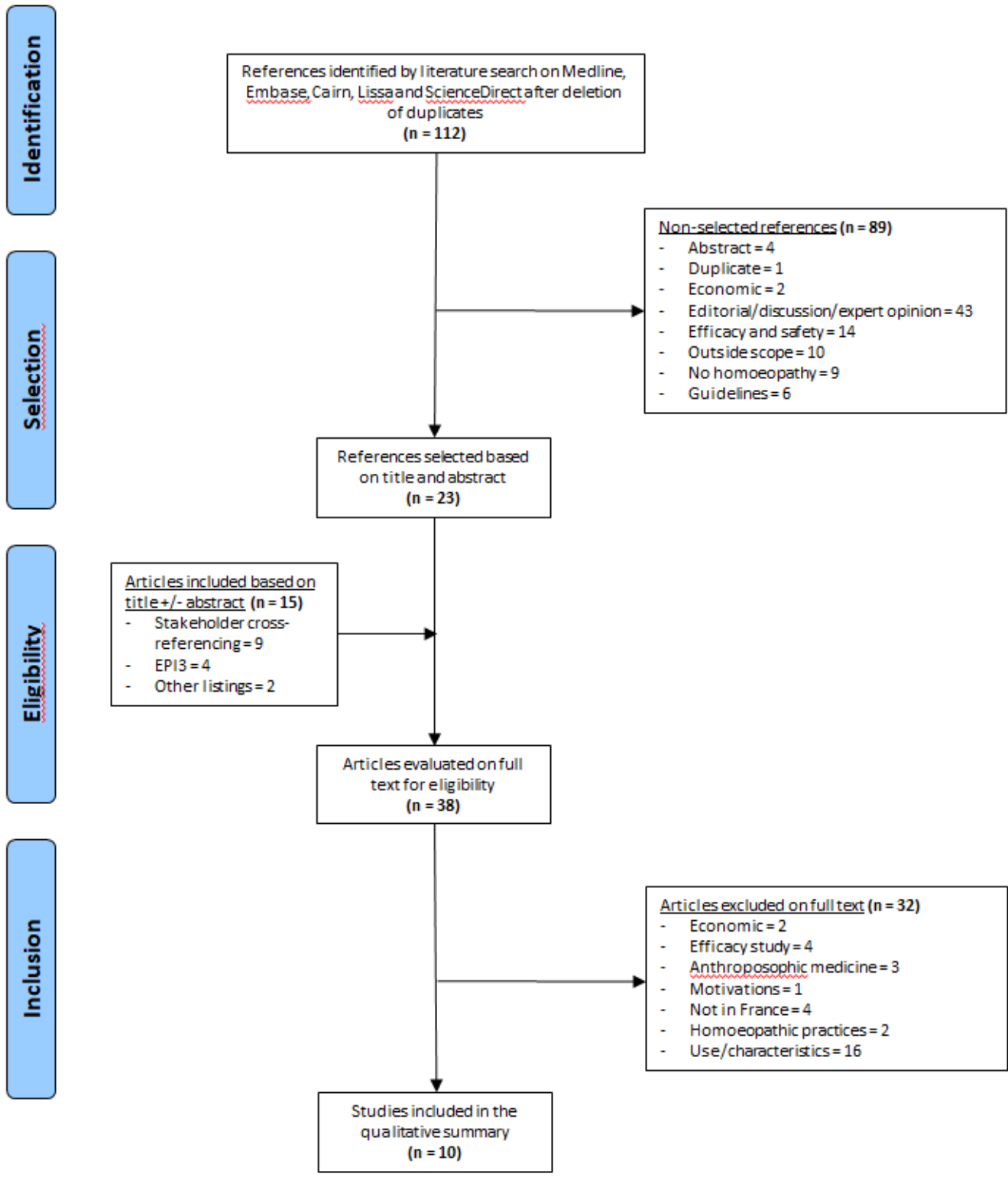
## APPENDIX 2: SLR/MA PRISMA FLOW DIAGRAM



## APPENDIX 3: RCT PRISMA FLOW DIAGRAM



# APPENDIX 4: PHB PRISMA FLOW DIAGRAM



## ANNEXE 5 : TABLEAU DES ETUDES DEPOSEES PAR LES LABORATOIRES

|    |   |
|----|---|
| 1  | Bellavite <i>and al.</i> , 2006. "Immunology and homeopathy. 4. Clinical studies-part 2" <i>Evidence-based Complementary and Alternative Medicine</i> .   |
| 2  | Bellavite <i>and al.</i> , 2011. "Advances in homeopathy and immunology: a review of clinical research", <i>Frontiers in Bioscience</i> .   |
| 3  | Boehm <i>and al.</i> , 2014. "Homeopathy in the treatment of fibromyalgia--a comprehensive literature-review and meta-analysis", <i>Complementary Therapies in Medicine</i> .   |
| 4  | Bonne. O <i>and al.</i> , 2003. "A randomized, double-blind, placebo-controlled study of classical homeopathy in generalized anxiety disorder", <i>J Clin Psychiatry</i> .  |
| 5  | Bornhöft <i>and al.</i> , 2006. "Effectiveness, safety and cost-effectiveness of homeopathy in general practice - summarized health technology assessment", <i>Forsch Komplement-Medicine</i> .   |
| 6  | Brinkhaus B. <i>and al.</i> , 2006. "Homeopathic arnica therapy in patients receiving knee surgery: Results of three randomised double-blind trials", <i>Complement Ther Med</i> .  |
| 7  | Danno <i>and al.</i> , 2018. "Management of anxiety and depressive disorders in patients ≥ 65 years of age by Homeopath general practitioners vs conventional general practitioners, with overview of the EPI3-LASER study results", <i>Homeopathy</i> .                    |
| 8  | Dean ME. <i>and al.</i> , 2012. "Homeopathy for mental fatigue: lessons from a randomized, triple blind, placebo-controlled cross-over clinical trial", <i>BMC Complement Altern Med</i> .  |
| 9  | Ernst <i>and al.</i> , 2012. "Homeopathy for eczema: a systematic review of controlled clinical trials", <i>British Journal of Dermatology</i> .  |
| 10 | Fisher P. <i>and al.</i> , 2001. "A randomized controlled trial of homeopathy in rheumatoid arthritis", <i>Rheumatology (Oxford)</i> .  |
| 11 | Fixsen <i>and al.</i> , 2018. "Homeopathy in the Age of Antimicrobial Resistance: Is It a Viable Treatment for Upper Respiratory Tract Infections?", <i>Homeopathy</i> .  |
| 12 | Frass. M <i>and al.</i> , 2005. "Influence of potassium dichromate on tracheal secretions in critically ill patients", <i>Chest</i> .   |
| 13 | Gibson RG <i>and al.</i> , 1985. "Homeopathic therapy in rheumatoid arthritis: Evaluation by double-blind clinical therapeutic trial", <i>Br J Clin Pharmacol</i> .   |
| 14 | Grimaldi-Bensouda <i>and al.</i> , 2015. "Utilization of psychotropic drugs by patients consulting for sleeping disorder in homeopathic and conventional primary care settings: The EPI3 cohort", <i>Homeopathy</i> .   |
| 15 | Grimaldi-Bensouda <i>and al.</i> , 2016. "Homeopathic medical practice for anxiety and depression in primary care: the EPI3 cohort study", <i>BMC complementary and alternative medicine</i> .  |
| 16 | Haidvogel M <i>and al.</i> , 2007. "Homeopathic and conventional treatment for acute respiratory and ear complaints: a comparative study on outcome in the primary care setting", <i>BMC Complement Altern Med</i> .  |
| 17 | Hamre <i>and al.</i> , 2005, <i>Anthroposophic vs. conventional therapy of acute respiratory &amp; ear infections: a prospective outcomes study</i> , <i>Wien Klin Wochenschr</i> .   |
| 18 | Hamre <i>and al.</i> , 2013, <i>Long-term outcomes of anthroposophic treatment for chronic disease: a four-year follow-up analysis of 1510 patients from a prospective observational study in routine outpatient settings</i> , <i>BMC</i> .                                |
| 19 | Heirs <i>and al.</i> , 2007. "Homeopathy for attention deficit/hyperactivity disorder OR hyperkinetic disorder", <i>Cochrane</i>  |
| 20 | Jacobs J. <i>and al.</i> , 2001. Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial, <i>Pediatr Infect Dis J</i> . 2001 Feb;20(2):177-83.   |
| 21 | Karp <i>and al.</i> , 2016. "Treatment with <i>Ruta graveolens</i> 5CH and <i>Rhus toxicodendron</i> 9CH may reduce joint pain and stiffness linked to aromatase inhibitors in women with early breast cancer: results of a pilot observational study", <i>Homeopathy</i> . |
| 22 | Kassab <i>and al.</i> , 2009. "Homeopathic medicines for adverse effects of cancer treatments", <i>Cochrane</i> .   |
| 23 | Kienle <i>and al.</i> , 2011, <i>Klinische Forschung zur Anthroposophischen Medizin—Update eines Health Technology Assessment- Berichts und Status Quo</i> . <i>Forsch Komplementmed</i> . 2011; 18:269-82  |
| 24 | Leone <i>and al.</i> , 2011. "Measuring the effectiveness of homeopathic care through objective and shared indicators", <i>Homeopathy</i> .   |
| 25 | Lewith GT <i>and al.</i> , 2002. "Use of ultramolecular potencies of allergen to treat asthmatic people allergic to house dust mite", <i>BMJ</i> .  |
| 26 | Linde <i>and al.</i> , 1997. "Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials", <i>Lancet</i>  |
| 27 | Pilington <i>and al.</i> , 2005. "Homeopathy for depression: a systematic review of the research evidence", <i>Homeopathy</i> .   |
| 28 | Pomposelli R. <i>and al.</i> , 2009. "Observational study of homeopathic and conventional therapies in patients with diabetic polyneuropathy", <i>Homeopathy</i> .  |
| 29 | Reilly D.T. <i>and al.</i> , 1986 "Is homeopathy a placebo response? Controlled trial of homeopathic potency, with pollen in hay fever as model", <i>Lancet</i> .   |
| 30 | Rosignol <i>and al.</i> , 2012. <i>Impact of physician preferences for homeopathic OR conventional medicine on patients with musculoskeletal disorders: results from the EPI-MSD cohort</i> , <i>Pharmacoepidemiol Drug Saf</i> . Oct;21(10):1093-101                       |
| 31 | Steinsbekk <i>and al.</i> , 2005. "Patients' assessments of the effectiveness of homeopathic care in Norway: a prospective observational multicentre outcome study", <i>Homeopathy</i> .  |
| 32 | Straumsheim P <i>and al.</i> , 2000. "Homeopathic treatment of migraine: a double blind, placebo-controlled trial of 68 patients" <i>Br Homeopath J</i> .   |
| 33 | Taylor M.A. <i>and al.</i> , 2000. "Randomised controlled trial of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series", <i>BMJ</i> .   |
| 34 | Tveiten D. <i>and al.</i> , 2003. "Effect of Arnica D30 in marathon runners. Pooled results from two double-blind placebo-controlled studies", <i>Homeopathy</i> .  |
| 35 | Van Wassenhoven <i>and al.</i> , 2014. "Pediatric homeopathy: a prospective observational survey based on parent proxy-reports of their children's health-related Quality of Life in six European countries and Brazil", <i>Homeopathy</i> .                                |
| 36 | Waisse-Priven S. <i>and al.</i> , 2009. "Individualized homeopathic treatment of dermatological complaints in a public outpatient clinic", <i>Homeopathy</i> .  |
| 37 | Weatherley-Jones E. <i>and al.</i> , 2004. "A randomised, controlled, triple-blind trial of the efficacy of homeopathic treatment for chronic fatigue   |

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|    | <i>syndrome</i> ”, J Psychosom Res.   |
| 38 | White A <i>and al.</i> , 2003. “ <i>Individualised homeopathy as an adjunct in the treatment of childhood asthma: a randomised placebo-controlled trial</i> ”, Thorax.  |
| 39 | Witt <i>and al.</i> , 2005. “ <i>Outcome and costs of homeopathic and conventional treatment strategies: a comparative cohort study in patients with chronic disorders</i> ”, <i>Complementary Therapies in Medicine</i> .  |
| 40 | Witt <i>and al.</i> , 2009. “ <i>Homeopathic treatment of patients with psoriasis - a prospective observational study with 2 years follow-up</i> ”, J Eur Acad Dermatol Venereol.   |
| 41 | Witt CM. <i>and al.</i> , 2009. “ <i>Homeopathic versus conventional therapy for atopic eczema in children: medical and economic results</i> ”, <i>Dermatology</i> .  |
| 42 | Zanasi A <i>and al.</i> , 2014. “ <i>Homeopathic medicine for acute cough in upper respiratory tract infections and acute bronchitis</i> ”, Pulm Pharmacol Ther.  |
| 43 | Zanasi <i>and al.</i> , 2015. “ <i>Does additional antimicrobial treatment have a better effect on URTI cough resolution than homeopathic symptomatic therapy alone?</i> ”, <i>Multidiscip Respir Med</i> .   |
| 44 | Kim L.S. <i>and al.</i> , 2005. “ <i>Treatment of Seasonal Allergic Rhinitis Using Homeopathic Preparation of Common Allergens in the Southwest Region of the US: A Randomized, Controlled Clinical Trial</i> ”, Ann Pharmacother.  |
| 45 | MC <i>and al.</i> , 2010. “ <i>Homeopathic treatment of patients with migraine: a prospective observational study with a 2-year follow-up period</i> ”, J Altern Complement Med.  |
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| 47 | Baars <i>and al.</i> , 2006, “ <i>Safety of Homeopathic Injectables for Subcutaneous Administration: A Document of the Experience of Prescribing Practitioners</i> ”.   |
| 48 | Bell. I. R <i>and al.</i> , 2004. “ <i>Improved clinical status in fibromyalgia patients treated with individualized homeopathic remedies versus placebo</i> ”, <i>Rheumatology</i> (Oxford).   |
| 49 | Bellavite <i>and al.</i> , 2006. “ <i>Immunology and homeopathy. 4. Clinical studies-part 1</i> ”, <i>Evidence-based Complementary and Alternative Medicine</i> .   |
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| 52 | Chapman. E <i>and al.</i> , 1999. “ <i>Homeopathic treatment of mild traumatic brain injury: A randomized, double-blind, placebo-controlled clinical trial</i> ”, J Head Trauma Rehabil.  |
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| 54 | Cucherat <i>and al.</i> , 2000. “ <i>Evidence of clinical efficacy of homeopathy. A meta-analysis of clinical trials. HMRAG. Homeopathic Medicines Research Advisory Group</i> ”. <i>European Journal of Clinical Pharmacology</i> .  |
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| 56 | Danno K <i>and al.</i> , 2013. “ <i>Homeopathic treatment of migraine in children: results of a prospective, multicenter, observational study</i> ”, J Altern Complement Med.   |
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| 58 | Ernst <i>and al.</i> , 2010. “ <i>Homeopathy: what does the "best" evidence tell us?</i> ”, <i>The Medical Journal of Australia</i> .   |
| 59 | Fischer-Lokou. Poster « <i>Aconitum napellus D30 en solution injectable dans le traitement des douleurs d’origine neurologique</i> », Colloque RHAPID   |
| 60 | Fixsen <i>and al.</i> , 2013. “ <i>Should homeopathy be considered as part of a treatment strategy for otitis media with effusion in children?</i> ”, <i>Homeopathy</i> .   |
| 61 | Frass. M <i>and al.</i> , 2005. “ <i>Adjunctive homeopathic treatment in patients with severe sepsis: a randomized, double-blind, placebo-controlled trial in an intensive care unit</i> ”, <i>Homeopathy</i> .   |
| 62 | Frei. H <i>and al.</i> , 2005. “ <i>Homeopathic treatment of children with attention deficit hyperactivity disorder: a randomised, double blind, placebo-controlled crossover trial</i> ”, Eur J Pediatr.   |
| 63 | Grimaldi-Bensouda <i>and al.</i> , 2014. “ <i>Management of upper respiratory tract infections by different medical practices, including homeopathy and consumption of antibiotics in primary care: the EPI-3 cohort study in France 2007-2008</i> ”, PLOS ONE  |
| 64 | Gründling C <i>and al.</i> , 2012. “ <i>Real-life effect of classical homeopathy in the treatment of allergies</i> ”, Wien Klin Wochenschr.   |
| 65 | Hamre <i>and al.</i> , 2017, Glockmann A, Heckenbach K, Matthes H; <i>Use and Safety of Anthroposophic Medicinal Products: An Analysis of 44,662 Patients from the EvaMed Pharmacovigilance Network; Drugs - Real World Outcomes</i> .  |
| 66 | Hamre <i>and al.</i> , 2018, <i>A 4-year non-randomized comparative phase-IV study of early rheumatoid arthritis: integrative anthroposophic medicine for patients with preference against DMARDs vs. conventional therapy including DMARDs for patients without preference. Patient Preference and Adherence</i> . |
| 67 | Hawke <i>and al.</i> , 2018. “ <i>Homeopathic medicinal products for preventing and treating acute respiratory tract infections in children</i> ”, Cochrane   |
| 68 | Jacobs J. <i>and al.</i> , 2003. <i>Homeopathy for childhood diarrhea: combined results and meta-analysis from three randomized, controlled clinical trials</i> . Pediatr Infect Dis J. 2003 Mar;22(3):229-34.  |
| 69 | Kainz J.T. <i>and al.</i> , 1996. “ <i>Homeopathic versus placebo therapy of children with warts on the hands: a randomized, double-blind clinical trial</i> ”, <i>Dermatology</i> .  |
| 70 | Keil T <i>and al.</i> , 2008. “ <i>Homeopathic versus conventional treatment of children with eczema: a comparative cohort study</i> ”, <i>Complement Ther Med</i> .  |
| 71 | Kienle <i>and al.</i> , 2006, <i>Anthroposophic medicine: effectiveness, utility, costs, safety</i> . Stuttgart, NY: Schattauer Verlag; 2006.   |
| 72 | Kleijnen <i>and al.</i> , 1991. “ <i>Clinical trials of homeopathy</i> ”, British Medical Journal.  |

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## APPENDIX 6: STAKEHOLDERS SURVEY

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### Assessment of homoeopathic medicinal products - *contribution from interested parties* -

The questionnaire below aims to collect your view point of interested parties on homoeopathic medicines.

Your contribution must only include medicinal products currently reimbursed by the French health insurance scheme and should be presented by condition or symptom type. Your answers must specify the type of information used and must be supported, where applicable, by citing the sources. Financial arguments will not be taken into account.

1 (\*) **What is your status?**

Patient or users association     Professional union     Learned society     Professional board     Medicine/pharmacy academy

2 (\*) **Name of your structure:**

•

3 (\*) **E-mail:**

•

4 **In your opinion, for which type of conditions or symptoms can homoeopathic medicines be used?**

No more than 5,000 characters

5 **For these types of conditions or symptoms, what are the clinical advantages and disadvantages of homoeopathy, in particular with respect to the alternatives available?**

No more than 5,000 characters

6

**According to your structure, what is the impact of homoeopathy on organization of care?**

No more than 5,000 characters

7

**Additional information:**

No more than 5,000 characters

8

**How did you go about answering this questionnaire?**

*State the type of information used to complete the questionnaire (e.g. Search, social media, working group, witness statements, literature analysis, expert opinion etc.)*

No more than 1,000 characters

9

**List of sources and references used for your contribution:**

No more than 5,000 characters

10(\*)

**Summary of your contribution:**

*List the most important aspects of your contribution*

No more than 2,000 characters

## APPENDIX 7: STUDIES SELECTED FOR THE ANALYSIS

| Therapeutic area                | Health condition                              | Efficacy/safety  |   | PHB  |
|---------------------------------|---|--|---|--|
|                                 |   | SLR/MA   | RCT   |  |
| <b>ONCOLOGY SUPPORTIVE CARE</b> | Adverse effects of cancer drugs               | Kassab, 2009 (15)<br>Milazzo, 2006 (16)<br>Rada, 2010 (17) | -   | -  |
| <b>POISONING</b>                | Lead poisoning                                | -  | Padilha, 2011 (18)                              | -  |
| <b>DERMATOLOGY</b>              | Non-genital warts                             | Simonart, 2012 (19)  | -   | -  |
| <b>NEUROLOGY</b>                | Headaches/migraine                            | Saha, 2013 (20)  | -   | -  |
| <b>FUNCTIONAL DISORDERS</b>     | Chronic fatigue syndrome                      | Alraek, 2011 (21)  | -   | -  |
| <b>RHEUMATOLOGY</b>             | Arthritis                                     | Koley, 2013 (22)   | -   | -  |
|                                 | Rheumatoid arthritis                          | Macfarlane, 2011 (23)<br>Phang, 2018 (24)                  | -   | -  |
|                                 | Musculoskeletal disorders                     | -  | -   | Danno, 2014 (25)<br>Rossignol, 2012 (26)         |
| <b>PAIN/TRAUMATOLOGY</b>        | Post-operative inflammation                   | Ho, 2016 (27)<br>Barlow, 2013 (28)                         | Cornu, 2010 (29)                                | -  |
|                                 | Post-operative pain                           | Keefe, 2018 (30)<br>Raak, 2012 (31)                        | Paris, 2008 (32)                                | -  |
| <b>PAEDIATRICS</b>              | Infantile diarrhoea/gastroenteritis           | -  | Jacobs, 2000 (33)<br>Jacobs, 2006 (34)          | -  |
|                                 | Acute respiratory tract infection             | Hawke, 2018 (35)   | -   | -  |
|                                 | Acute otitis media                            | -  | Jacobs, 2001 (36)<br>Pedrero-Escalas, 2016 (37) | -  |
|                                 | Post-vaccination febrile episode              | -  | Ghosh, 2018 (38)                                | -  |
| <b>GYNAECOLOGY</b>              | Labour induction                              | Smith, 2003 (39)   | -   | -  |
|                                 | Withdrawal of lactation                       | Oladapo, 2012 (40)   | -   | -  |
|                                 | Vulvar-vaginal candidiasis                    | -  | Witt, 2009 (41)                                 | -  |
| <b>CHEST MEDICINE</b>           | Asthma  | McCarney, 2004 (42)  | -   | -  |
|                                 | Allergic rhinitis                             | Banerjee, 2017 (43)  | -   | -  |
|                                 | Respiratory tract infections                  | -  | -   | Grimaldi-Bensouda, 2014 (44)                     |
| <b>PSYCHIATRY</b>               | Anxiety                                       | Pilkington, 2006 (45)                                      | -   | Danno, 2018 (46)<br>Grimaldi-Bensouda, 2016 (47) |
|                                 | Depression                                    | -  | Macia-cortes, 2015 (48)                         | -  |
|                                 | Sleep disorders                               | -  | -   | Grimaldi-Bensouda, 2015 (49)                     |
|                                 | Attention and hyperactivity deficit disorders | Catala-Lopez, 2017 (50)                                    | -   | -  |
| <b>OVERALL SAFETY</b>           | -   | Stub, 2016 (51)  | -   | -  |

## APPENDIX 8 : TABLE OF STUDIES EXCLUDED ON FULL TEXT

| Study                            | Health condition                             | Reason for exclusion                     |
|----------------------------------|--|--|
| <b>Efficacy and safety (RCT)</b> |  |  |
| Aabel, 2000 (52)                 | Rhinitis                                     | Already included in SLR                  |
| Aabel, 2000 (53)                 | Rhinitis                                     | Already included in SLR                  |
| Aabel, 2001 (54)                 | Rhinitis                                     | Already included in SLR                  |
| Adkison, 2010 (55)               | Muscle pain                                  | Reference not received                   |
| Adler, 2011 (56)                 | Depression                                   | Outside scope (dilution)                 |
| Adler, 2013 (57)                 | Depression                                   | Outside scope (dilution)                 |
| Adler, 2018 (58)                 | Cocaine withdrawal                           | Outside scope (dilution)                 |
| Alizadeh, 2006 (59)              | Dysmenorrhoea                                | Insufficient numbers                     |
| Andrade, 2019 (60)               | Hot flushes                                  | Reference not received                   |
| Baker, 2003 (61)                 | Anxiety                                      | Insufficient numbers                     |
| Balzarini, 2000 (62)             | Oncology supportive care                     | Already included in SLR                  |
| Beer, 2012 (63)                  | Lower back pain                              | German                                   |
| Bell, 2004 (64)                  | Fibromyalgia                                 | Already included in SLR                  |
| Bellavite, 2006 (65)             | Immunology                                   | No RCT (or SLR)                          |
| Belon, 2007 (66)                 | Arsenic poisoning                            | Insufficient numbers                     |
| Ben-Arye, 2003 (67)              | Psoriasis                                    | Reference not received                   |
| Berrebi, 2001 (68)               | Withdrawal of lactation                      | Already included in SLR                  |
| Bonne, 2003 (69)                 | Anxiety                                      | Insufficient numbers                     |
| Brewitt, 2002 (70)               | HIV  | No RCT (Works)                           |
| Brien, 2011 (71)                 | Rheumatoid arthritis                         | Already included in SLR                  |
| Brinkhaus, 2006 (72)             | Post-operative pain                          | Already included in SLR                  |
| Cavalcanti, 2003 (73)            | Pruritus                                     | Reference not received                   |
| Chaïet, 2016 (74)                | Oedema/bruising                              | Out of scope (medicinal product with MA) |
| Chand, 2014 (75)                 | Tuberculosis                                 | Rejection on PICOTS                      |
| Chauhan, 2014 (76)               | Hypothyroidism                               | Outside scope (dilution)                 |
| Colau, 2012 (77)                 | Hot flushes                                  | Out of scope (medicinal product with MA) |
| De Verdier, 2003 (78)            | Diarrhoea                                    | Studies on animals                       |
| Del Castillo, 2014 (79)          | Obesity/excess weight                        | No RCT (or SLR)                          |
| Dorey, 2002 (80)                 | -  | Letter/comment                           |
| Feder, 2002 (81)                 | -  | Letter/comment                           |
| Ferrara, 2008 (82)               | Nocturnal enuresis                           | Does not related to homeopathy           |
| Fisher, 2001 (83)                | Rheumatoid arthritis                         | Already included in SLR                  |
| Frass, 2005                      | Tracheal secretions                          | Reference not received                   |
| Frass, 2005 (84)                 | Sepsis                                       | Reference not received                   |
| Frass, 2015 (85)                 | Oncology supportive care                     | Open-label study                         |
| Frei, 2005 (86)                  | Attention and hyperactivity deficit disorder | Outside scope (dilution)                 |
| Friese, 2001 (87)                | Pharyngeal adenoids                          | Outside scope (dilution)                 |
| Friese, 2007 (88)                | Rhinitis                                     | German                                   |
| Gmunder, 2002 (89)               | Lower back pain                              | German                                   |
| Haila, 2005 (90)                 | Dry mouth                                    | Insufficient numbers                     |
| Heudel, 2018 (91)                | Oncology supportive care                     | Out of scope (medicinal product with MA) |
| Hyland, 2002 (92)                | Asthma                                       | Rejection on PICOTS                      |
| Jacobs, 2005 (93)                | Oncology supportive care                     | Already included in SLR                  |
| Jeffrey, 2002 (94)               | Post-operative pain                          | Already included in SLR                  |
| Kern, 2014 (95)                  | Rhinitis                                     | No RCT (or SLR)                          |
| Khuda-bukhsh, 2005 (96)          | Lead poisoning                               | No RCT                                   |
| Khuda-bukhsh, 2011 (97)          | Arsenic toxicity                             | Outside scope (dilution)                 |
| Klein-Lansmaa, 2018 (98)         | Premenstrual syndrome                        | Open-label study                         |

|                                      |                                   |   |
|--------------------------------------|-----------------------------------|---|
| <b>Kotlus, 2010 (99)</b>             | Oedema/bruising                   | Insufficient numbers                                  |
| <b>La Pine, 2006 (100)</b>           | Jet lag                           | Rejection on PICOTS                                   |
| <b>Leckridge, 2002 (101)</b>         | -                                 | Letter/comment  |
| <b>Leite, 2008 (102)</b>             | Obesity/excess weight             | Thesis  |
| <b>Macia-cortes, 2017 (103)</b>      | Menopause                         | Post hoc analysis / no RCT                            |
| <b>Macia-cortes, 2018 (104)</b>      | Menopause                         | Post hoc analysis / no RCT                            |
| <b>MacLennan, 2009 (105)</b>         | Menopause                         | No RCT (or SLR)                                       |
| <b>Misael, 2014 (106)</b>            | Obesity/excess weight             | No RCT (or SLR)                                       |
| <b>Morris, 2016 (107)</b>            | Osteoarthritis                    | Insufficient numbers                                  |
| <b>Mourao, 2013 (108)</b>            | Periodontitis                     | Insufficient numbers                                  |
| <b>Mourao, 2014 (109)</b>            | Periodontitis                     | Insufficient numbers                                  |
| <b>Mousavi, 2009 (110)</b>           | Ulcers                            | Poor reporting quality, no outcome measures announced |
| <b>Oberai, 2018 (111)</b>            | Encephalic syndrome               | Reference not received                                |
| <b>Oberbaum, 2005 (112)</b>          | <i>Post-partum</i> haemorrhage    | Preliminary results (study ongoing)                   |
| <b>Paterson, 2003 (113)</b>          | Dyspepsia                         | Insufficient numbers                                  |
| <b>Peckham, 2014 (114)</b>           | Irritable bowel syndrome          | Intermediate results                                  |
| <b>Reilly, 2002 (115)</b>            | -                                 | Letter/comment  |
| <b>Reinhard-Hennch, 2006 (116)</b>   | Menopause                         | German  |
| <b>Relton, 2009 (117)</b>            | Fibromyalgia                      | Already included in SLR                               |
| <b>Relton, 2012 (118)</b>            | Hot flushes                       | Insufficient numbers                                  |
| <b>Robertson, 2007 (119)</b>         | Post-operative pain               | Already included in SLR                               |
| <b>Sanchez-Navarette, 2016 (120)</b> | Obesity/excess weight             | Spanish   |
| <b>Schmidt, 2002 (121)</b>           | Diabetes                          | Already included in SLR                               |
| <b>Seeley, 2006 (122)</b>            | Oedema/bruising                   | Insufficient numbers                                  |
| <b>Shah, 2013 (123)</b>              | Hepatitis C                       | Reference not received                                |
| <b>Singh, 2015 (124)</b>             | Obesity                           | Insufficient numbers                                  |
| <b>Sinha, 2012 (125)</b>             | Otitis                            | Outside scope (dilution)                              |
| <b>Sorrentino, 2017 (126)</b>        | Oncology supportive care          | Outside scope (dilution)                              |
| <b>Steinsbekk, 2005 (127)</b>        | Acute respiratory tract infection | Already included in SLR                               |
| <b>Stevinson, 2003 (128)</b>         | Pain                              | Already included in SLR                               |
| <b>Straumshein, 2000 (129)</b>       | Neurology                         | Already included in SLR                               |
| <b>Sujee, 2009 (130)</b>             | Diabetes                          | Thesis  |
| <b>Taylor, 2000 (131)</b>            | Rhinitis                          | Already included in SLR                               |
| <b>Taylor, 2011 (132)</b>            | Acute otitis media                | Rejection on PICOTS                                   |
| <b>Teixeira, 2017 (133)</b>          | Endometriosis                     | Out of scope  |
| <b>Thachil, 2007 (134)</b>           | Depression                        | Out of scope  |
| <b>Thompson, 2005 (135)</b>          | Oncology supportive care          | Already included in SLR                               |
| <b>Tiwari, 2010 (136)</b>            | Diabetes                          | Reference not received                                |
| <b>Van Haselen, 2000 (137)</b>       | Osteoarthritis                    | Out of scope (medicinal product with MA)              |
| <b>Viksveen, 2017 (138)</b>          | Depression                        | Open-label study                                      |
| <b>Vilhena, 2016 (139)</b>           | Diabetes                          | Reference not received                                |
| <b>Voss, 2018 (140)</b>              | Dry cough                         | Reference not received                                |
| <b>Weatherley-Jones, 2004 (141)</b>  | Chronic fatigue syndrome          | Already included in SLR                               |
| <b>White, 2003 (142)</b>             | Asthma                            | Already included in SLR                               |
| <b>Wolf, 2003 (143)</b>              | Oedema/bruising                   | German  |
| <b>Yakir, 2001 (144)</b>             | Premenstrual syndrome             | Insufficient numbers                                  |
| <b>Zafar, 2016 (145)</b>             | Labour pain                       | Outside scope (dilution)                              |
| <b>Zanasi, 2013 (146)</b>            | Acute respiratory tract infection | Already included in SLR                               |
| <b>Efficacy and safety (SLR/MA)</b>  |                                   |   |
| <b>Achuthan, 2015 (147)</b>          | Snoring                           | Out of scope (medicinal product with MA)              |
| <b>Altunc, 2007 (148)</b>            | -                                 | General SLR   |

|                                      |  |  |
|--------------------------------------|--|--|
| <b>Antonelli, 2018 (149)</b>         | -  | No SLR/MA  |
| <b>Asher, 2015 (150)</b>             | Rhinitis                                     | Reference not received   |
| <b>Astrid-Becerra, 2012 (151)</b>    | Stopping smoking                             | Spanish  |
| <b>Atif, 2018(152)</b>               | Palliative treatment                         | Reference not received   |
| <b>Banerjee, 2014 (43)</b>           | Allergic rhinitis                            | Protocol   |
| <b>Bao, 2014 (153)</b>               | Oncology supportive care                     | SLR from SLR   |
| <b>Baranowsky, 2009 (154)</b>        | Fibromyalgia                                 | Outside scope (dilution)   |
| <b>Behrens-baumann, 2006 (155)</b>   | Ophthalmo                                    | German   |
| <b>Bellavite, 2011 (156)</b>         | Immuno                                       | Reference not received   |
| <b>Bevilaqua, 2003 (157)</b>         | Post-operative pain                          | Reference not received   |
| <b>Boehm, 2014 (158)</b>             | Fibromyalgia                                 | Insufficient numbers   |
| <b>Boltman-Binkowski, 2016 (159)</b> | Safety                                       | Rejection on PICOTS  |
| <b>Brouwer, 2018 (160)</b>           | Psychiatric disorders                        | Rejection on PICOTS  |
| <b>Carillo, 2003 (161)</b>           | -  | Spanish  |
| <b>Catala-Lopez, 2015 (162)</b>      | Attention and hyperactivity deficit disorder | Protocol   |
| <b>Chakraborti, 2003 (163)</b>       | Arsenic poisoning                            | No SLR/MA  |
| <b>Chambers, 2006 (164)</b>          | Chronic fatigue syndrome                     | SLR having included the same RCTs already exists (Alraeck, 2011)               |
| <b>Cooper, 2010 (165)</b>            | Insomnia                                     | No SLR/MA  |
| <b>Cooper, 2010 (166)</b>            | Insomnia                                     | Out of scope   |
| <b>Cucherat, 2000 (167)</b>          | -  | General SLR  |
| <b>Dantas, 2000 (168)</b>            | Safety                                       | No references  |
| <b>Davidson, 2011 (169)</b>          | Psychiatry                                   | Rejection on PICOTS  |
| <b>De Nonneville, 2018 (170)</b>     | Oncology supportive care                     | SLR having included the same RCTs already exists (Kassab, 2009 and Rada, 2010) |
| <b>De Silva, 2010 (171)</b>          | Fibromyalgia                                 | Outside scope (dilution) and insufficient numbers                              |
| <b>De Silva, 2011 (172)</b>          | Osteoarthritis                               | SLR having included the same RCTs already exists (Koley, 2013)                 |
| <b>Dole, 2012 (173)</b>              | Pain   | Reference not received   |
| <b>Ernst, 2002 (174)</b>             | -  | SLR from SLR   |
| <b>Ernst, 2010 (175)</b>             | -  | SLR from SLR   |
| <b>Ernst, 2011 (176)</b>             | Allergies                                    | Rejection on PICOTS  |
| <b>Ernst, 2011 (177)</b>             | Allergic rhinitis                            | Rejection on PICOTS  |
| <b>Ernst, 2012 (178)</b>             | Eczema                                       | Rejection on PICOTS  |
| <b>Fisher, 2015 (179)</b>            | -  | No SLR/MA  |
| <b>Fixsen, 2013 (180)</b>            | Otitis                                       | Rejection on PICOTS  |
| <b>Gaertner, 2017 (181)</b>          | -  | Abstract   |
| <b>Gagnier, 2007 (182)</b>           | Lower back pain                              | Updated in 2014 (Oltean, 2014)   |
| <b>Gagnier, 2008 (183)</b>           | Lower back pain                              | Out of scope (medicinal product with MA)                                       |
| <b>Goncalo, 2014 (184)</b>           | Oral health                                  | Poor reporting quality, the studies are not described                          |
| <b>Gosik, 2017 (185)</b>             | Autism                                       | German   |
| <b>Grabia, 2003 (186)</b>            | Safety                                       | General SLR  |
| <b>Gupta, 2014 (187)</b>             | Seborrhoeic dermatitis                       | Rejection on PICOTS  |
| <b>Gyorik, 2004 (188)</b>            | Asthma                                       | SLR having included the same RCTs already exists (McCarney, 2004)              |
| <b>Hahn, 2013 (189)</b>              | -  | No SLR/MA  |
| <b>Hauser, 2008 (190)</b>            | Fibromyalgia                                 | Treatment guidelines   |
| <b>Heirs, 2007 (191)</b>             | Attention and hyperactivity deficit disorder | SLR having included the same RCTs already exists (Catala-Lopez, 2017)          |

|   |  |   |
|---|--|---|
| <b>Hidalgo, 2007 (192)</b>  | Anxiety                                      | SLR having included the same RCTs already exists (Pilkington, 2006) |
| <b>Hoare, 2000 (193)</b>  | Eczema                                       | Reference not received  |
| <b>Holdcraft, 2003 (194)</b>                                      | Fibromyalgia                                 | Insufficient numbers  |
| <b>Huang, 2011 (195)</b>  | Enuresis                                     | No homeopathy RCT   |
| <b>Hunt, 2006 (196)</b>   | -  | SLR from SLR  |
| <b>Unknown, 2006 (197)</b>  | Dengue/chikungunya                           | Protocol  |
| <b>Unknown, 2010 (198)</b>  | -  | German  |
| <b>Unknown, 2013 (199)</b>  | -  | Reference not received  |
| <b>Jacobs, 2003 (200)</b>   | Infantile diarrhoea                          | No SLR/MA   |
| <b>Johnson, 2018 (201)</b>  | Oncology supportive care                     | No SLR/MA   |
| <b>Jonas, 2000 (202)</b>  | Rheumatism                                   | No SLR/MA   |
| <b>Joos, 2011 (203)</b>   | Chronic inflammatory bowel diseases          | No homeopathy RCT   |
| <b>Jyothis, 2011 (204)</b>  | Oncology supportive care                     | No SLR/MA   |
| <b>Keen, 2008 (205)</b>   | Attention and hyperactivity deficit disorder | Updated in 2011   |
| <b>Keen, 2011 (206)</b>   | Attention and hyperactivity deficit disorder | Reference not received  |
| <b>Kim, 2013 (207)</b>  | Chronic fatigue syndrome                     | SLR having included the same RCTs already exists (Alraeck, 2011)    |
| <b>Koretz, 2006 (208)</b>   | -  | No SLR/MA   |
| <b>Kusse, 2011 (209)</b>  | -  | German  |
| <b>Langhorst, 2012 (210)</b>                                      | Fibromyalgia                                 | German  |
| <b>Levi, 2013 (211)</b>   | Otitis                                       | Rejection on PICOTS   |
| <b>Linde, 2001 (212)</b>  | -  | SLR from SLR  |
| <b>Linde, 2006 (213)</b>  | -  | General SLR   |
| <b>Long, 2001 (214)</b>   | Osteoarthritis                               | SLR having included the same RCTs already exists (Koley, 2013)      |
| <b>Loo, 2009 (215)</b>  | Non-genital warts                            | Reference not received  |
| <b>Lüdtke, 2005 (216)</b>   | Pain   | German  |
| <b>Madhok, 2016 (217)</b>   | Eczema                                       | SLR from SLR  |
| <b>Marom, 2016 (218)</b>  | Otitis                                       | Rejection on PICOTS   |
| <b>Mathie, 2003 (219)</b>   | -  | General SLR   |
| <b>Mathie, 2014 (220)</b>   | -  | General SLR   |
| <b>Mathie, 2015 (221)</b>   | -  | No SLR/MA   |
| <b>Mathie, 2017 (222)</b>   | -  | Abstract  |
| <b>Mathie, 2017 (223)</b>   | -  | General SLR   |
| <b>Mathie, 2018 (224)</b>   | -  | Abstract  |
| <b>Mathie, 2018 (225)</b>   | -  | General SLR   |
| <b>Mc Carney, 2003 (226)</b>                                      | Dementia                                     | No homeopathy RCT   |
| <b>Mc Carney, 2004 (227)</b>                                      | Asthma                                       | SLR from SLR  |
| <b>Milazzo, 2005 (228)</b>  | Oncology supportive care                     | Abstract  |
| <b>Mills, 2005 (229)</b>  | HIV  | Rejection on PICOTS   |
| <b>Mittelstadt, 2013 (230)</b>                                    | Sports injuries                              | Reference not received  |
| <b>Monami, 2018 (231)</b>   | Diabetes/obesity                             | No homeopathy RCT   |
| <b>Myers, 2002 (232)</b>  | Facial pain                                  | No homeopathy RCT   |
| <b>Nai-ming, 2007 (233)</b>                                       | Non-genital warts                            | Reference not received but updated (Loo, 2009)                      |
| <b>National Collaborating Centre for Primary Care, 2007 (234)</b> | Chronic fatigue syndrome                     | Treatment guidelines  |
| <b>Oltean, 2014 (235)</b>   | Lower back pain                              | Out of scope (medicinal product with MA)                            |
| <b>Owen, 2004 (236)</b>   | Headaches/migraine                           | SLR having included the same RCTs already exists (Saha, 2013 #63)   |

|                              |  |  |
|------------------------------|--|--|
| Passalacqua, 2006 (236)      | Rhinitis                                     | Treatment guidelines   |
| Peckham, 2013 (237)          | Irritable bowel syndrome                     | Outside scope (dilution)   |
| Perry, 2010 (238)            | Fibromyalgia                                 | Outside scope (dilution) and insufficient numbers                |
| Pilkington, 2005 (239)       | Depression                                   | Insufficient numbers   |
| Pittler, 2005 (240)          | Obesity/excess weight                        | Follow-up period non relevant                                    |
| Porter, 2010 (241)           | Chronic fatigue syndrome                     | SLR having included the same RCTs already exists (Alraeck, 2011) |
| Quinn, 2006 (242)            | Lower back pain                              | Out of scope (medicinal product with MA)                         |
| Qureshi, 2013 (243)          | Depression                                   | Rejection on PICOTS  |
| Reid, 2008 (244)             | Chronic fatigue syndrome                     | Updated in 2011 (Reid, 2011)                                     |
| Reid, 2011 (245)             | Chronic fatigue syndrome                     | SLR having included the same RCTs already exists (Alraeck, 2011) |
| Riemann, 2017 (246)          | Insomnia                                     | Treatment guidelines   |
| Roberts, 2012 (247)          | Post-operative pain                          | SLR having included the same RCTs already exists (Barlow, 2013)  |
| Saha, 2013 (248)             | HIV  | Rejection on PICOTS  |
| Saha, 2013 (249)             | Rheumatoid arthritis                         | Reference not received   |
| Sales, 2018 (250)            | Post-chikungunya chronic arthritis           | No homeopathy RCT  |
| Sarris, 2011 (251)           | Insomnia                                     | No homeopathy RCT  |
| Schwermer, 2018 (252)        | Gastroenteritis                              | German   |
| Searight, 2011 (253)         | Attention and hyperactivity deficit disorder | Rejection on PICOTS  |
| Shaddel, 2014 (254)          | Intellectual deficit                         | Rejection on PICOTS  |
| Shang, 2005 (255)            | -  | Reference not received   |
| Simonart, 2011 (256)         | -  | General SLR  |
| Sinsen, 2010 (257)           | Infertility                                  | Reference not received   |
| Spigelblatt, 2005 (258)      | -  | Reference not received   |
| Stevinson, 2001 (259)        | Premenstrual syndrome                        | Insufficient numbers   |
| Tabbers, 2011 (260)          | Infantile constipation                       | No homeopathy RCT  |
| Thandar, 2014 (261)          | Eczema                                       | Rejection on PICOTS  |
| Torley, 2013 (262)           | Eczema                                       | No SLR/MA  |
| Ullman, 2003 (263)           | HIV  | Rejection on PICOTS  |
| Ullman, 2010 (264)           | Allergies                                    | Rejection on PICOTS  |
| Van der Wouden, 2017 (265)   | <i>Molluscum contagiosum</i>                 | Insufficient numbers   |
| Viksveen, 2018 (266)         | Depression                                   | Search period too short  |
| Walach, 2005 (267)           | -  | SLR from SLR   |
| Walach, 2006 (268)           | -  | No SLR/MA  |
| Weiner, 2004 (269)           | Muscle pain                                  | No SLR/MA  |
| Whiting, 2001 (270)          | Chronic fatigue syndrome                     | SLR having included the same RCTs already exists (Alraeck, 2011) |
| Wiesenaer, 2000 (271)        | Rhinitis                                     | Abstract   |
| Witt, 2000 (272)             | Infertility                                  | Abstract   |
| Yaju, 2013 (273)             | Bleeding on birth                            | Preliminary/intermediate results                                 |
| <b>Public health benefit</b> |  |  |
| Abitbol, 2014 (274)          | Chronic inflammatory bowel disease           | Use data/patient characteristics                                 |
| Bensoussan, 2006 (275)       | Chronic inflammatory bowel disease           | Use data/patient characteristics                                 |
| Chaufferin, 2000 (276)       | -  | Economic   |
| Colas, 2015 (277)            | -  | Economic   |
| Colin, 2000 (278)            | -  | Homeopathic practices  |
| Danno, 2016 (279)            | Oncology                                     | Patient motivation studies                                       |
| Dupin, 2018 (280)            | Oncology                                     | Use data/patient characteristics                                 |



|                                      |                               |  |
|--------------------------------------|-------------------------------|--|
| <b>Frenkel, 2002 (281)</b>           | Allergology                   | Not in France  |
| <b>Grimaldi-bensouda, 2011 (2)</b>   | -                             | Use data/patient characteristics                       |
| <b>Grimaldi-bensouda, 2012 (282)</b> | Anxiety and depression        | Use data/patient characteristics                       |
| <b>Haidvogel, 2007 (283)</b>         | Respiratory diseases          | Therapeutic efficacy (non-randomised trial)            |
| <b>Hamre, 2005 (284)</b>             | Respiratory and ear infection | Outside scope (anthroposophic medicine), not in France |
| <b>Hamre, 2013 (285)</b>             | Chronic diseases              | Therapeutic efficacy (non-randomised trial)            |
| <b>Hamre, 2014 (286)</b>             | Respiratory and ear infection | Outside scope (anthroposophic medicine), not in France |
| <b>Hamre, 2017 (287)</b>             | -                             | Outside scope (anthroposophic medicine)                |
| <b>Hamre, 2018 (288)</b>             | Rheumatoid arthritis          | Therapeutic efficacy (non-randomised trial)            |
| <b>Lert, 2014 (3)</b>                | -                             | Use data/patient characteristics                       |
| <b>Philibert, 2015 (289)</b>         | Oncology                      | Use data/patient characteristics                       |
| <b>Pirolot, 2015 (1)</b>             | -                             | Use data/patient characteristics                       |
| <b>Riley, 2001 (290)</b>             | -                             | Therapeutic efficacy (non-randomised trial)            |
| <b>Rosignol, 2011 (291)</b>          | Musculoskeletal disorders     | Use data/patient characteristics                       |
| <b>Rosignol, 2011 (292)</b>          | Musculoskeletal disorders     | Use data/patient characteristics                       |
| <b>Saghatchian, 2014 (293)</b>       | Oncology                      | Use data/patient characteristics                       |
| <b>Sarradon-Erck, 2017 (294)</b>     | Oncology                      | Use data/patient characteristics                       |
| <b>Simon, 2007 (295)</b>             | Oncology                      | Use data/patient characteristics                       |
| <b>Taylor, 2014 (296)</b>            | Acute otitis media            | Not in France  |
| <b>Trager-maury, 2007 (297)</b>      | Oncology                      | Use data/patient characteristics                       |
| <b>Trichard, 2003 (298)</b>          | -                             | Homeopathic practices                                  |
| <b>Viksveen, 2017 (138)</b>          | Depression                    | Not in France  |
| <b>Villet, 2016 (299)</b>            | Anxiety and depression        | Use data/patient characteristics                       |
| <b>Vincent, 2013 (300)</b>           | Seasonal influenza            | Use data/patient characteristics                       |
| <b>Walker, 2018 (301)</b>            | -                             | Not in France  |

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