

# Stand van zaken van de homeopathie in België

KCE reports 154A

# Het Federaal Kenniscentrum voor de Gezondheidszorg

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Conflict of interest: Norbert Fraeyman (Ugent) doceert over alternatieve geneeskunde en

publiceerde zijn collegenota's onder boekvorm.

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- Vervolgens werd een (finale) versie aan de <u>validatoren</u> voorgelegd. De validatie van het rapport volgt uit een consensus of een meerderheidsstem tussen de validatoren. Zij zijn geen coauteur van het wetenschappelijk rapport en gingen niet

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- Tot slot werd dit rapport unaniem goedgekeurd door de Raad

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aanbevelingen aan de overheid.

Layout : Ine Verhulst

Brussel, 24 mei 2011 Studie nr 2009-50

Domein: Health Services Research (HSR)

MeSH: Homeopathy (adverse effects, education, legislation and jurisprudence, organization and administration, statistics and numerical data, trends, utilization); Treatment Outcome; Qualitative

Research; Belgium

NLM Classificatie: WB 930 Taal: Nederlands, Engels

Formaat: Adobe® PDF™ (A4)

Wettelijk depot: D/2011/10.273/12

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Hoe refereren naar dit document?

De Gendt T, Desomer A, Goossens M, Hanquet G, Léonard C, Mertens R, Piérart J, Robays J, Roberfroid D, Schmitz O, Vinck I, Kohn L. Stand van zaken van de homeopathie in België. Health Services Research (HSR). Brussel: Federaal Kenniscentrum voor de Gezondheidszorg (KCE). 2011. KCE Reports 154A. D/2011/10.273/12.



# **VOORWOORD**

Voor u ligt het derde en laatste KCE rapport over niet-conventionele geneeswijzen. Het gaat over de homeopatie, die van alle bestudeerde niet-conventionele geneeswijzen tegelijk het meest en het minst gelijkenis heeft met de klassieke evidence-based geneeskunde. Het meest omdat de homeopathie vooral beoefend wordt door artsen en zich bezig houdt met een ruime waaier gezondheidsproblemen, net zoals de algemene geneeskunde. Het minst omdat zij absoluut niet kan bogen op wetenschappelijke bewijzen, in tegenstelling tot de andere bestudeerde niet-conventionele geneeswijzen die toch enige, zij het beperkte geloofsbrieven konden voorleggen.

Nochtans heeft de homeopathie zeer veel trouwe of occasionele aanhangers, die ondanks het gebrek aan bewijzen niet geneigd zijn haar de rug toe te keren. Op basis van hun eigen gunstige ervaringen hebben zij zich een mening gevormd, waar zij niet zomaar wensen van af te stappen.

Het kan niet de bedoeling van het KCE zijn om de overtuigingen van hen die er rotsvast in geloven te gaan wijzigen. Onze rol is veeleer, zoals gewoonlijk, om wetenschappelijke elementen aan te dragen om de beleidsmakers te helpen bij hun besluitvorming. Meer concreet komt het erop aan om de eventuele risico's van deze niet-conventionele aanpak zo efficiënt mogelijk te beheersen zonder daarom volledig het kind met het badwater weg te gooien.

Wij hopen hierin geslaagd te zijn dankzij, opnieuw, een multidisciplinaire en strakke aanpak. Wij danken al wie ons bij deze uitdagende oefening heeft geholpen. Een oefening waarin men erin geslaagd is om ook oor te hebben voor minder vertrouwde standpunten en toch de eigen ethische en wetenschappelijk standaarden hoog te houden.

Jean Pierre CLOSON

Adjunct algemeen directeur

**Raf MERTENS** 

Algemeen directeur

# Samenvatting

## KADER VAN HET ONDERZOEK

Op verzoek van de Minister van Volksgezondheid en Sociale Zaken maakte het KCE een stand van zaken op voor de vier niet-conventionele geneeswijzen die sinds 1999 in België erkend zijn door de "wet Colla", nl. acupunctuur, homeopathie, chiropraxie en osteopathie. Deze geneeswijzen worden gedefinieerd als een « groep van diverse medische en gezondheidszorgsystemen, praktijken en producten die momenteel niet worden beschouwd als deel uitmakend van de conventionele geneeskunde" a. Deze therapieën worden betiteld als 'aanvullend' wanneer ze samen met conventionele behandelingen worden gebruikt en als 'alternatief' wanneer ze in de plaats van een conventionele behandeling worden gebruikt.

Dit rapport is de laatste in een reeks van drie: na de osteopathie en chiropraxie en na de acupunctuur, hebben we de homeopathie geanalyseerd en meer bepaald de praktijk en de therapeuten. We hebben ons toegespitst op de therapeuten die zich als homeopaat profileren en op de patiënten die homeopathie gebruiken door specifiek een homeopaat te consulteren. We zijn in dit rapport niet ingegaan op de problematiek rond de homeopatische middelen.

De homeopathie, een methode ontwikkeld door Dr. Samuel Hahnemann in het begin van de XIX<sup>de</sup> eeuw, bestaat uit het toedienen van preparaten die worden bereid op basis van een oertinctuur die sterk verdund en gepotentieerd wordt. Homeopathie berust op een aantal principes:

- De similia-regel die stelt dat "stoffen die bepaalde symptomen veroorzaken in een verder gezond lichaam, soortgelijke symptomen in een ziek persoon genezen". Met elk homeopathisch middel van dierlijke, plantaardige of minerale oorsprong, worden dus symptomen geassocieerd die een gezonde persoon zou vertonen mocht hij deze stof innemen.
- De beginselen van sterke verdunning en van potentiëring door het krachtig schudden van het middel, wat de "interne kracht van de substanties" zou vrijmaken die op de levenskracht van de zieke kunnen inwerken.
- De wet van de individualisering van de behandeling ("er zijn geen ziekten, alleen maar zieken"), die wordt gebruikt in samenhang met het begrip van de "constitutie" van de patiënt.

In België wordt de homeopathie al bijna 200 jaar door artsen beoefend, en sinds kort ook door niet-artsen.

## **DOELSTELLINGEN**

Dit rapport heeft tot doel een antwoord te geven op volgende vragen:

- 1. Hoe doeltreffend is homeopathie? Wat zijn de voor- en nadelen?
- Welke definitie hanteert deze geneeswijze zelf en hoe wordt deze geneeswijze gebruikt door de Belgische bevolking.
- 3. Wat is het wettelijk statuut van de homeopathie en hoe is ze in België georganiseerd?
- 4. Hoe worden de homeopaten opgeleid?

a National Center for Complementary and Alternative Medicine; 2007 [cited 04/11/2008]. CAM Basics. Beschikbaar op: http://nccam.nih.gov/health/whatiscam/pdf/D347.pdf

## **METHODEN**

Om deze niet-conventionele geneeswijzen in hun complexiteit te kunnen bevatten, opteerde het KCE voor een multidimensionale benadering, die tegelijkertijd medisch, sociologisch, antropologisch, juridisch en organisatorisch is. Voor elk van deze dimensies deed het KCE een beroep op aangepaste methoden:

- een systematisch overzicht van de wetenschappelijke literatuur bedoeld om de klinische doeltreffendheid en veiligheid van de homeopathie te evalueren,
- een telefonische enquête bij een representatieve steekproef van de algemene populatie (n=2000), bedoeld om na te gaan in welke mate van nietconventionele therapieën gebruik wordt gemaakt,
- een enquête aan de hand van semi-gestructureerde socio-antropologische interviews bedoeld om de percepties van de regelmatige gebruikers (n=9) en van de homeopaten (n=10) te begrijpen,
- een online enquête bij de homeopaten met de vraag om hun profiel en praktijk te beschrijven (n=144/330),
- een gedetailleerde analyse van het juridisch en organisatorisch kader en van de uitdagingen, en tenslotte,
- het raadplegen van de beroepsverenigingen en -organisaties en van deskundigen om te kunnen beschrijven hoe de homeopathie georganiseerd is en hoe de beoefenaars worden opgeleid.

# **RESULTATEN**

## KLINISCHE DOELTREFFENDHEID EN RISICO'S

## Geen enkel bewijs van doeltreffendheid

De gepubliceerde studies hebben de doeltreffendheid van de homeopathie onderzocht voor volgende indicaties: slapeloosheid, allergische rinitis, lumbalgie, verloskundige indicaties, chronische vermoeidheid, dementie, astma, bedwateren, depressie, angst, symptomen veroorzaakt door kanker of de behandeling ervan, opvliegers, kinderziekten, aandachtstekortstoornis met hyperactiviteit (ADHD), fibromyalgie, HIV, chronische veneuze insufficiëntie, en premenstrueel syndroom.

Geen enkele van deze studies heeft de doeltreffendheid van homeopathie kunnen aantonen, ondanks de goede kwaliteit van onderzoek van sommige van deze studies. Het klinisch effect is niet te onderscheiden van een placebo-effect, dat overigens goed gekend en bewezen is.

### Geen bijwerkingen, maar wel secundaire risico's

Er werd geen enkele bijwerking aangetoond na behandeling met homeopathie.

Er zijn gevallen gemeld van laattijdige opstart of afwezigheid van een doeltreffende behandeling, maar dit risico kan niet nauwkeurig worden ingeschat.

Ten slotte is ook het risico op het zich niet laten vaccineren tijdens begeleiding van een homeopaat beschreven, maar de literatuur is tegenstrijdig en zijn geen gegevens voorhanden voor België.

# **TOESTAND IN BELGIE**

## Wettelijk kader

Het wettelijke kader is in principe gelijkaardig voor alle niet-conventionele praktijken, namelijk de wet "Colla", uitgevaardigd op 29 april 1999. Een algemene discussie over dit wettelijke kader kan in het wetenschappelijk rapport teruggevonden worden.

Het stellen van een diagnose en het opstarten van een behandeling voor een lichamelijke of geestelijke aandoening is volgens de wet voorbehouden aan personen die een diploma in de geneeskunde hebben. Homeopaten die een diagnose stellen en/of een behandeling opstarten in het kader van hun beroep zonder arts te zijn, werken dus in de illegaliteit.

## Gebruik: vooral voor algemene klachten

In 2009 had 6% van de ondervraagde personen (telefonische enquête) een homeopaat geraadpleegd in de loop van de laatste 12 maanden. Over het algemeen verwerpen deze patiënten de conventioneel geneeskunde niet, maar doen ze een beroep op deze geneeswijze op een aanvullende manier, waarbij ze sommige indicaties voorbehouden voor de homeopathie en andere voor de conventionele geneeskunde. De beslissing om te consulteren wordt ingegeven door advies van familieleden of kennissen. De patiënten geven aan dat ze een homeopaat voornamelijk raadplegen voor rug- of nekpijn, allergie, of vermoeidheid. Echter, volgens de beoefenaars die de online enquête beantwoordden (homeopaten die lid zijn van een beroepsvereniging) wordt de homeopaat ook geconsulteerd voor klachten met betrekking tot het ademhalingsstelsel en problemen van depressie en angst. Het patiëntenbestand is samengesteld uit alle leeftijdscategorieën.

Uit kwalitatieve gesprekken met de gebruikers blijkt dat de zoektocht naar een ander type geneeskunde, meer gericht op de natuur, minder agressief en meer geïndividualiseerd ook een reden is voor het gebruik van de homeopathie.

Het percentage tevreden patiënten ligt bij niet-conventionele therapeuten in het algemeen vrij dicht bij het percentage dat wordt genoteerd voor de conventionele geneeskunde.

#### Wie zijn de therapeuten?

Begin 2011 zijn er ongeveer 340 homeopaten aangesloten bij een beroepsvereniging in België. Dit aantal dekt waarschijnlijk niet het totale aantal van de artsen die homeopathie toepassen.

De homeopaten behoren tot verschillende stromingen die samenhangen met het soort middelen dat ze gebruiken en of ze die al dan niet combineren: unitair (of klassiek), complex of klinisch<sup>b</sup>. De leden van de beroepsverenigingen zijn voornamelijk aanhangers van de enkelvoudige (klassieke) homeopathie.

Uit de online enquête die werd uitgevoerd bij deze groep blijkt dat 75% arts is, maar ook dat een vijfde van de homeopaten nooit een (para)medische opleiding heeft gehad.

In deze specifieke groep van therapeuten is twee derde tot deze therapeutische benadering gekomen omdat ze zelf behandeld werden door een homeopaat en in 31% omdat een familielid of een vriend door deze therapie werd geholpen.

De klassieke of unitaire homeopaten, trouw aan de beginselen van Hahnemann, zijn op zoek naar een uniek middel aangepast aan de individuele patiënt. De beoefenaars van complexe of meervoudige homeopathie schrijven een combinatie van "contextuele" en "fundamentele" middelen. De klinische homeopaten geven de voorkeur aan de homeopathische middelen die inwerken op een bepaald orgaan of systeem. Deze middelen kunnen al dan niet van complexe samenstelling zijn, maar hebben meestal een lage verdunning.

## Hoe zijn de homeopaten opgeleid?

Er bestaan verschillende opleidingsnetwerken voor homeopathie in België. Voor artsen zijn er meerdere scholen, gegroepeerd in een 'faculteit voor homeopathie', die een opleiding in unitaire homeopathie over een periode van 3 tot 5 jaar (deeltijds) aanbieden. Eén centrum stelt een opleiding in 'klinische' homeopathie voor die wordt gespreid over 6 weekends gedurende 2 jaar.

Voor de niet-artsen bestaat er een weekend-opleiding in unitaire (klassieke) homeopathie over een periode van 5 jaar (waarbij 33 van de 180 studiepunten besteed worden aan medische cursussen).

## Hoe zijn de homeopaten georganiseerd?

De homeopaten hebben zich gegroepeerd in twee beroepsorganisaties. Ze zijn allebei geregistreerd in het kader van de wet Colla. De Unio Homeopathica Belgica (UHB) telt iets meer dan 300 leden (begin 2011) en verenigt artsen, dierenartsen, tandartsen of apothekers die een diploma hebben dat erkend is door de "faculteit voor homeopathie". De Liga Homeopathica Classica (LHC) telt 40 leden, 'klassieke' homeopaten, al dan niet arts (de helft heeft geen enkele medische opleiding). Deze twee beroepsverenigingen verdedigen de "klassieke" homeopathie.

#### De consultaties

Volgens de gegevens van de online enquête bij de beroepsbeoefenaars, werken 58% van de ondervraagden homeopaten in Vlaanderen, 20% in Wallonië en 22% in Brussel.

In de praktijk duurt de eerste consultatie tussen I uur en I uur 30, soms meer, voor een volwassene. De opvolgingsconsultaties en de consultaties voor kinderen zijn korter.

Een patiënt zal 4 tot 6 keer worden gezien tijdens het I<sup>ste</sup> jaar en I tot 3 keer tijdens het volgende jaar.

De patiënten krijgen een of meerdere middelen voorgeschreven die zij in de apotheek moeten gaan halen.

Eventuele daarop volgende ziekte-episodes kunnen worden behandeld via zelfmedicatie met begeleiding via de telefoon. Indien er geen duidelijke verbetering van de symptomen optreedt binnen de 2 of 3 dagen zal de patiënt gevraagd worden om een afspraak te maken.

Naast de homeopatische producten worden soms ook andere producten of 'natuurlijke' bereidingen aan de patiënten aangereikt.

# Financiële aspecten

Uit onze verschillende enquêtes blijkt dat de homeopathische consultaties tussen 50 en 80 euro kunnen kosten voor een eerste consultatie voor een volwassene en tussen 35 en 80 euro voor een kind. De opvolgingsconsultaties kosten zelden meer dan 50 euro. Er is geen enkele terugbetaling door de verplichte ziekteverzekering voorzien, tenzij voor de consultatie van de arts, in voorkomend geval. Sommige ziekenfondsen komen echter onder bepaalde voorwaarden tussenbeide in het kader van hun aanvullende verzekering en dit geldt ook voor sommige privéverzekeringen.

# **CONCLUSIE**

Ondanks talrijke pogingen is er geen enkele publicatie van goede kwaliteit die enig bewijs kan aanvoeren voor een grotere doeltreffendheid van homeopathie dan deze van placebo. Anderzijds wordt er evenmin enige bijwerking aangetoond.

De patiënten zoeken in de homeopathie een niet-medicamenteuze, natuurlijke therapie zonder bijwerkingen. Jaarlijks doet ongeveer 6% van de bevolking een beroep op deze niet-conventionele geneeswijze en is er over het algemeen tevreden over.

De niet-arts homeopaten beoefenen de homeopathie momenteel in de illegaliteit en de patiënten hebben geen enkele garantie van overheidswege wat betreft de veiligheid en de kwaliteit van zorg.

Rekening houdend met de zeer brede waaier aan redenen waarom wordt geconsulteerd en de 'generalistische' aanpak die homeopaten zich aanmeten, is de kennis van de beoefenaar op het vlak van diagnose en conventionele behandelingen daarom essentieel, en de vereiste competenties zijn moeilijk te onderscheiden van die voor een arts. Het uitoefenen van homeopathie door een homeopaat die ook houder is van een medisch diploma, laat toe het risico op het uitstellen of het missen van een diagnose en het risico op het onthouden van een nodige conventionele behandeling te beheersen.

De opleidingen die momenteel aan de niet-artsen worden gegeven dekken niet noodzakelijk voldoende de domeinen die toelaten de veiligheid van de patiënt te garanderen. Wat de homeopathische artsen betreft, bestaat het risico dat hun geneeskundige kennis niet meer up-to-date blijft, als zij alleen permanente bijscholing volgen op het vlak van de homeopathie.

# **AANBEVELINGEN<sup>c</sup>**

- Gezien de grote verscheidenheid aan consultatieredenen en de "algemene benadering" waarop door homeopaten aanspraak wordt gemaakt, beveelt het KCE aan om de toegang tot deze geneeswijze te beperken tot de artsen die voldoen aan alle wettelijke voorwaarden om de geneeskunde uit te oefenen.
- Aangezien voor geen enkele medische indicatie wetenschappelijk werd aangetoond dat de werkzaamheid van homeopathische behandelingen superieur zou aan deze van placebo, wordt hun terugbetaling door de verplichte ziekteverzekering niet aanbevolen.
- Als men beslist om de uitoefening van homeopathie enkel toe te laten voor artsen, kan men zich de vraag stellen of, buiten de registratie van deze therapie als niet-conventionele geneeswijze en de registratie van haar beoefenaars, de wet Colla een meerwaarde biedt voor de praktijk van deze therapie.
- De verdunningen die worden gehanteerd bij het bereiden van de homeopathische geneesmiddelen en, desgevallend, hun officiële registratie, maken dat het gebruik ervan geen enkel rechtstreeks risico met zich meebrengt. Dit is niet noodzakelijk het geval het geval voor een reeks andere producten die vaak worden geassocieerd of verward met homeopathie en die verkocht worden als geneesmiddel of voedingssupplement zonder dezelfde garanties voor kwaliteit en veiligheid als geneesmiddelen. Hierover moeten de gebruikers beter worden geïnformeerd.

Het KCE blijft als enige verantwoordelijk voor de aanbevelingen die aan de overheid worden geformuleerd.

# **Scientific Summary**

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# **ABREVIATIONS**

AETSA Andalusian Agency for Health Technology Assessment

AHB Association Homéopathique Belge
AMED Allied and Complementary Medicine

AR Arrêté Royal

BDMA Belgian Direct Marketing Association

BIG (loi) (Wet) Beroepen in de Individuele Gezondheidszorg

BMA Bristish Medical Association

CAM Complementary and Alternative Medicine
CATI Computer Assisted Telephone Interviewing
CDSR Cochrane Database of Systematic Reviews

CEDH Centre for Education and Development of Clinical Homeopathy

CEN Comité Européen de Normalisation European committee for Standardization

CBHU Centre Bruxellois d'Homéopathie

CI Confidence Interval

CINHAL Cumulative Index of Nursing and Allied Health Literature

CKH Centrum voor Klassieke Homeopathie

CLH Centre Liégois d'Homéopathie

CRD Centre for Reviews and Dissemination

DNA Deoxyribonucleic acid

EBH Ecole Belgde d'Homéopathie
EBM Evidence Based Medicine

ECH European Committee for Homeopathy

ECCH European Central Council of Homeopaths/ European Council for Classical

Homeopathy

EFHPA European Federation of Homeopathic Patients' Association

FNRS Fonds National de le Recherche Scientifique

HIV Human immunodeficiency virus
HTA Health Technology Assesment

ICH International Council of Homeopathy

INSERM Institut national de la santé et de la recherche médicale
ISKH Internationale School voor Klassieke Homeopathie
IAMA The Journal of the American Medical Association

LHC Liga Homeopathica Classica

LMHI Liga Medicorum Homeopathica Internationalis

MB Moniteur Belge
MD Mean Difference

MeSH Medical Subject Heading
MWD Mean Weighted Difference

NCCAM National Center for Complementary and Alternative Medicine

NICE National Institute for Health and Clinical Excellence

NRS Numerical Rating Scale

NSAID Non Steroidal Anti-inflammatory Drug
PEDro Physiotherapy Evidence Database
RCT Randomised Controlled Trial

RD Royal Decree

RMDQ Roland Morris Disability Questionnaire

RR Relative Risk

SIGN Scottish Intercollegiate Guidelines Network

SMD Standardised Mean Difference

SPF Service Public Fédéral

SRBH The Royal Belgian society of homeopathy

TCM Traditional Chinese Medicine

TENS Transcutanuous Electric Nerve Stimulation

UHB Unio Homoeopathica Belgica

UK United Kingdom

ULB Université Libre de Bruxelles US(A) United States (of America)

VAS Visual Analog Scale

VATAP Veterans Affairs Technology Assessment Program

VSU Vlaamse Studievereniging voor Unitaire homeopathische geneeskunde

WAD Whiplash Associated Disorder
WHO World Health Organization
WMD Weighted Mean Difference

WMHTAG West Midlands Health Technology Assessment Group WVTS Wetenschappelijke Vereniging voor TherapieStudie

WUG Wet op de Uitoefening der Geneeskunst

# I INTRODUCTION

## I.I BACKGROUND

Acupuncture, chiropractic, osteopathy and homeopathy are practices classified as complementary and alternative medicine. In 2007, the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institute of Health (US) defined these medicines as a 'group of diverse medical and healthcare systems, practices and products that are not currently considered to be part of conventional medicine'. These therapies are referred to as 'complementary' where they are used jointly with conventional treatments, and as 'alternative' where they are used instead of conventional treatment.

Prior to this, in 1993, the British Medical Association<sup>1</sup> defined them as 'those forms of treatment which are not widely used by the orthodox health care professions and the skills of which are not taught as part of the undergraduate curriculum of orthodox medical and paramedical health care courses'.

The WHO defined them as: 'a broad set of health care practices that are not part of the country's own tradition and are not integrated into the dominant health care system'\*<sup>2</sup>.

In Belgium, performing a diagnosis and dispensing treatment for a physical or psychological disorder are legally restricted to the holders of a diploma of doctor of medicine approved by the competent medical commission (Royal Decree 78)<sup>3</sup>. In principle, only they can use Complementary and Alternative Medicines (CAMs) to care for patients. There are a number of treatments that can be dispensed legally by physiotherapists – on medical prescription – that may form part of a non-conventional treatment.

In 1999, a law concerning non-conventional medicines was promulgated. This law covers homeopathy, chiropractic, osteopathy and acupuncture, and also holds out the possibility of recognising other alternative or complementary therapies. The purpose of the law is to allow practitioners of these practices to be registered as such and to practice legally the non-conventional medicines concerned. For this to happen, the non-conventional practices must also be registered. The law establishes the creation of a joint commission (one for all four practices) and four chambers (one for each non-conventional medicine) to advise the Minister for Public Health on the practice of CAMs. This includes among others the conditions for the registration of practitioners and the practices themselves, treatments not authorised for non-doctor practitioners and membership of recognised professional unions.

Since 1999 very little of the Colla law has been executed. A Royal Decree and a ministerial order have been published, which describe the recognition procedure and the conditions for the recognition of professional unions for non-conventional practices. In addition, a number of professional unions have been recognised by this Royal Decree.

Ten years later, the law of 1999 has only been partially implemented because neither the commission nor the chambers have been established. At the end of 2010, a number of initiatives have been taken to execute the law. The Minister for Public Health and Social Affairs have meanwhile asked the Federal Healthcare Knowledge Centre (KCE) to draw up a report on the situation of these practices in order to review or implement the law of 1999.

The alternative medicines project includes the publication of three reports: the first published report dealt with osteopathy and chiropraxy; the second was devoted to acupuncture; this last one is dealing with homeopathy.

# 1.2 OBJECTIVES AND METHODS

The report aims to respond to the following questions:

- I. How effective are alternative medicine? What are their benefits and drawbacks?
- 2. How are these medicines defined and how are they used by the Belgian population?
- 3. What is the legal status of these medicines and how are they organised in Belgium?
- 4. How are the therapists trained?

To this aim, specific methodologies have been employed: an analysis of the literature to assess the clinical effectiveness and safety of the therapies under study; a telephone survey of a population sample to measure the use of these therapies; a socio-anthropological interview-based survey to gauge the perceptions of regular users and therapists; an online survey of practitioners to describe the practitioners and practices; a detailed analysis of the legal and organisational framework to help to understand the Colla law, the and issues; and finally meetings with the professional unions and experts to describe how these professions are organised and how their practitioners are trained.

We did not analyse in this report the problem of the homeopathic remedies and their use in the population.

# 1.3 HISTORICAL BACKGROUND

## 1.3.1 Definition of homeopathy

As defined in evidence-based guidelines on CAM, homeopathy is "a therapeutic method, often using highly diluted preparations of substances whose effects when administered to healthy subjects correspond to the manifestations of the disorder (symptoms, clinical signs and pathological states) in the unwell patient" (Ernst, p326)<sup>4</sup>. Homeopathy does not refer to conventional disease categories nor remedies. "The aim of the homeopaths is to match a patient's individual symptoms with a 'drug picture' (i.e. a set of symptoms caused by a remedy in healthy volunteers)" (Ernst, p326)<sup>4</sup>. As defined by physician-homeopaths, "homeopathy is a medical practice aiming at strengthening the natural homeostasis of the body and stimulating the immune system." (Van Wassenhoven, p49)<sup>5</sup>.

## 1.3.2 Homeopathy's origins

"Homeopathy is a system of medical practice that originated with the work of the German physician Dr. Samuel Hahnemann (1755-1843), who as well as being an experienced orthodox physician was also a competent chemist, a good mineralogist and botanist, and an able translator of eight different languages"6. At its origins, homeopathy claimed that it could produce a proven specific remedy for any given constellation of circumstances and symptoms. This claim resulted from the particular answer that Dr. Samuel Hahnemann gave during the XIXth century to the following question: "did diseases exist as specific and knowable entities separate from the bodies in which they were expressed, or was every patient's disease experience unique and particular?" (Bivins, p91)7. Hahnemann was very sceptic about on what he regarded as speculative disease entities. He argued that the symptoms were the disease: "illness is the sum of its symptoms" (Bivins, p92)<sup>7</sup> Hahnemann laid out the fundamentals of homeopathy in the 'Organon of Medicine' (1810, revised six times),. 'Materia Medica Pura' (1811) records the symptoms of the medicine provings. In his book, 'The Chronic Diseases, Their Peculiar Nature and Their Homeopathic Cure' (1828), he showed how the natural diseases become chronic in nature6.

## 1.3.3 Three key principles

Homeopathy is built on three key principles: the law of similars, the law of infinitesimals and the globality.

## 1.3.3.1 The law of similars

"The law of similars or 'like cures like' principle states that a remedy which causes a certain symptom (e.g. a headache) in healthy volunteers can be used to treat a headache in patients who suffer from it" (Ernst, p326)<sup>4</sup>. This law was rooted in self experimented quinine effects by Hahnemann himself: "in 1790, Hahnemann deliberately ingested cinchona bark —rich in quinine- and experienced in consequence symptoms of the malarial fevers which that drug famously cured" (Bivins, p89)<sup>7</sup>. He initiated such experimentation -but with highly diluted substances- on himself and later on healthy volunteers to test these substances and describe the symptoms they caused. His idea was that "those substances which caused the symptoms of a particular disease in healthy person would relieve those symptoms in their sufferers" (Bivins, p89)<sup>7</sup>. This principle was termed similia similibus curentur (like treats like) by Hahnemann who thought he implemented the ancient Greek physician Hippocrates' idea of curing 'like with like', 2000 years after<sup>6</sup>. However, it is not clear if Hippocrates ideas can be interpreted like that.

## 1.3.3.2 The law of infinitesimals

"Homeopathic remedies are said by homeopaths to become stronger rather than weaker when submitted to 'potentisation', which describes the stepwise dilution combined with 'succussion', i.e. vigorous shaking of the mixture" (Ernst, p326)<sup>4</sup>. As explained by the homeopaths themselves, "The more stages of dilution and succussion the drug had gone through, the greater its potential to cure quickly and harmlessly"<sup>6</sup>. Potentization (or dynamization) is the combined process of serial dilution and succussion or trituration at each step in the manufacture of homeopathic medicines from stocks<sup>8</sup>. Dilution by I to I0 denotes I part processed with 9 parts of diluent (Hahnemannian decimal), dilution by I to I00, I part processed with 99 parts. Dilution ratio is up to I to 50000. The law of infinitesimals engendered polemical discussions around the question: what remains of the original substance after so a huge number of dilutions? This law was rooted in theoretical reasoning on the nature of disease<sup>7</sup> and, following the European Committee for Homeopathy (ECH) explanations, on Hahnemann's desire to minimise the harmful effects of the medicines which doctors were using<sup>6</sup>.

## 1.3.3.3 Globality

Globality in homeopathy suppose not to disentangle illness from the ill man but to consider them globally. Contextual information, individual constitution and individual reaction to disease in general have to be considered simultaneously with all the symptoms of a specific disease. After being synthesised, all these elements will help the homeopath to choose the appropriate drug.

# Conceptions of health and disease in homeopathy<sup>7</sup>

#### The healing power of nature:

• exploitation of the widespread belief in the healing power of nature, i.e. within all living bodies resided an innate healing power. Called "vitalisme" in France, this conception challenged the one of "determinisme" which grew in popularity with experimental medicine.

The model of the "self-limiting" disease:

 the natural course of a disease ends in a crisis during which the patient's vital force would either be exhausted or be restored.

Artificial disease to cure natural disease:

• The most effective therapeutic strategy was thought to strengthen the body for its inevitable ordeal, and to assist the nature in reaching the crisis before the body had been exhausted. The strong symptoms naturally induced by artificial disease extinguish the weaker effects of the natural disease.

## 1.3.4 19th century: the critique of heroic medicine

Homeopathy was founded mainly in reaction to the regular medicine of that time called "heroic medicine". "Both homeopathy and mesmerism presented themselves initially as radical innovations within established medicine" (Bivins, p 101)<sup>7</sup>. Modest as its origin, the critique became so intense, emanating from within the boundaries of medicine, that it drove "regular" practitioners to organize and identify as one profession. Two conceptions of medicine openly challenged each other when homeopaths were squeezed out by orthodox hostility<sup>7</sup>.

Two 19 <sup>th</sup> century conceptions of medicine <sup>7</sup>								
19th century Homeopathy	19 <sup>th</sup> century Heroic medicine							
Homeo-pathy as treatment with similars	Allo-pathy (a term forged by homeopaths) as							
	treatment with opposites							
Reinforcing the role of the patient as partner	Struggling to declare independence from the							
	patient							
Giving importance to the subjective experience	Giving importance to objective evidence of							
of illness	disease							
Every patient's disease experience is unique and	Disease exists as specific and knowable entities							
particular	separate from the bodies in which they were							
	expressed							
Tailored treatments	Standardized ways of healing							
Painless treatments	Painful treatments							

## 1.3.5 Migrations

From its origins as a critique from within the boundaries of elite German medicine, homeopathy spread rapidly to the rest of the wold. Quick translations of Hahnemann's books, wars and subsequent migrations, alleged success of homeopathy in helping to contain cholera epidemics, contributed to the spread of homeopathy into Europe and beyond. Pioneers played also an important role in this process, such as Comte Des Guidi in France (1830) who dedicated his life to homeopathy after his wife was "miraculously" healed by homeopathy.

"During the second half of the 19th century, homeopathy accompanied the waves of German immigrants to the United States. Homeopathy also expanded through the British Empire, the later Commonwealth countries such as India, Pakistan, Bangladesh, Sri Lanka, Australia, New Zealand, Nigeria, Ghana etc. Particularly in India and Pakistan homeopathy found an important breeding ground because of homeopathy's similarity with traditional Ayurvedic medicine"<sup>6</sup>.

#### 1.3.6 From master to masters<sup>9</sup>

The first Belgian homeopath was Dr. Pierre Joseph de Moor (1787-1845) who began to practice at Alost in 1829. In 1832, Dr. Varlez and Dr. Carlier brought homeopathy to Brussels. Dr Varlez opened the first homeopathic dispensary in Brussels. Dr. Jahr, one of Hahnemann's first followers, was practising homeopathy in Paris. But he had to flee Paris in 1870 during the Franco-German war and settled in Brussels to work in the Hahnemann dispensary. More than 50 Belgian doctors were educated in homeopathy by Jahr himself. In 1894, 70 doctors officially used homeopathy for their patients and 50 pharmacists were delivering medications to patients.

## 1.3.7 Self-organization

"The competition offered by the homeopathic system drove "regular" practitioners – previously absorbed by the internecine warfare between elite and general practitioners-to organize and identify as one profession". (Bivins, p99)<sup>7</sup> As in conventional medicine, homeopaths organize themselves with similar institutional devices: dispensaries or hospitals; schools; journals, libraries and conferences; associations for scientific, legal or political purpose; financial support (e.g. legacies); support from personalities (e.g. royal families); development of laboratories and specific pharmaceutical industry.

# Historic milestones of homeopathy in Belgium<sup>a</sup>

1835 : the earliest association for scientific purposes is founded by Dr Jahr (l'Association belge pour l'Homéopathie)

1855: the biggest homeopathic dispensary, the Hahnemann dispensary, opens his doors in Brussels (Dr de Molinari et Mouremans).

1856: the earliest journal was published in Brussels, La «Revue Internationale de Médecine Homéopathique» of Dr Jorez which shall become « la revue belge d'homeopathie », still published today.

1872-1920: a society of homeopathic physicians was established for scientific matters. The homeopathic medical circle of Flanders which will become the (royal) Belgian society of homeopathy.

1920: The (royal) Belgian society of homeopathy (SRBH) which is still active today and became "royal" in 1972.

1926-1976: the "Association Homéopathique Belge" (AHB) was created for legal purposes. This association created the Belgian Homeopathic School and started a Belgian Homeopathic Library

1956: the new Belgian School of Homeopathy was created by the SRBH besides private schools of Dr Schepens, Caulier and Hodiamont.

1970: a new "Fédération médicale homéopathique" is born to federate Belgian disparate tendencies of homeopathy

1985: project to federate belgian schools of unicist homeopathy into one "Belgian Faculty for homeopathic medicine"

1988: the "Unio Homoeopathica Belgica" (UHB) which was created for political purposes, was recognized by the Belgian authorities.

1999: with the Colla Law, a new professional union –the Liga Homeopathica Classica (LHC)- opened her door to non-physician homeopaths.

During the history of homeopathy, internal divisions occurred from time to time dividing masters, schools and methods. An important one distinguished the **classical homeopathic medicine** from the so-called "**complex homeopathy**". The first one is characterized by a 'unicist' approach where only one single remedy is prescribed, following the precepts of Hahnemann. The second one is characterized by a complexist approach where a combination of remedies is prescribed.

A second division occurred during these past ten years, separating lay-homeopaths from physician-homeopaths into distinct professional unions i.e. in Belgium the Liga Homeopathica Classica (lay-homeopaths) and the Unio Homoeopathica Belgica (physician-homeopaths). The lay-homeopaths (also called "professional homeopaths") have grown in number and visibility since the seventies, developing schools and professional unions<sup>10</sup>. In the UK, the lay homeopathy began in the seventies as a "cottage industry", taught in the homes of charismatic teachers, to become nowadays the largest organisation registering professional homeopaths in Europe -the Society of Homeopaths- with one leitmotiv "homeopathy for all" 11.

a Information about physician-homeopaths is detailed in (Van Wassenhoven, 1999)9

#### 1.3.8 Popularity history

During the 19<sup>th</sup> century, homeopathy was supported by a growing number of consumers dissatisfied with regular medicine. Medical historians discovered that "homeopathy has marketed itself in particular to women as a means by which to spare themselves and their children from the horrors of heroic medicine". Two kind of factors explaining the fluctuating popularity of homeopathy are found in literature: scientific or socio-economic. Some authors interpret this fluctuation as dependent on medical and scientific progress: "with the advent of effective drug treatments in the early part of the 20th century, its popularity decreased in most countries" (Ernst, p326)<sup>4</sup>. But others pinpoint socio-cultural reasons that gave strength to homeopathy. Medical historians have pointed out the important role of Catholicism in the French history of homeopathy. Similar rituals –stories about miracle cures, a charismatic leader (Hahnemann) and a fascinating book (the Organon)- but also common mistrust in science may explain the success of homeopathy within catholic circles of the 19<sup>th</sup> century<sup>12</sup>. Other non-medical explanations of the popularity of homeopathy are<sup>12</sup>:

- the development of homeopathic pharmaceutical industries and advertising at the beginning of the 20<sup>th</sup> century;
- the ecological preoccupations since the end of the 20<sup>th</sup> century.

## 1.3.9 The quest of scientific credibility

Since 1930 and the development of homeopathic pharmaceutical industries, a "modern homeopathy" was developed in France through schools, journals and research activities referring to Hahnemann as well as to Claude Bernard (experimental medicine)<sup>12</sup>. Nowadays, at European level, physician-homeopaths who looked at the scientific adequacy of their own discipline, concluded in 2008 that "the level of evidence obtained for numerous diagnoses is sufficient to accredit homeopathic practice in the scientific framework of the general practice".

Recent evolution of the Belgian legislation related to the registration of homeopathic remedies as medicines (Royal Decrees of 14/12/2006 and 20/12/2007), prompted the Belgian Royal Academy of Medicine and the Medical Council (Ordre des médecins/Orde van geneesheren) to reaffirm their position towards homeopathy. One year after its publication, the Belgian Royal Academy of Medicine gave an advice on this report called "Scientific framework of Homeopathy: Evidence based homeopathy". Against what the Academy considered as dogmatic conclusions (such as "the facts proposed in this report are indisputable"), she concluded that controversies are not closed but still open at both empirical and rational levels of the homeopathic pharmacology.

## 1.3.9.1 At empirical level

At empirical level, homeopaths are collecting internal evidences for two centuries with healthy volunteers who test homeopathic medicines on themselves. These "provings" are standardized and realised on a regular basis with placebo control. The ECH publishes on its website specific guidelines for provings. These provings confirmed by clinical verification on a relevant number of patients are considered by homeopaths to furnish a sufficient level of evidence. But for such instances as the Belgian Royal Academy of Medicine or the Medical Council, the lack of evidence of efficacy predominates.

### **Proving**

The medicine is taken by a volunteer for at least two consecutive days. The symptoms, developed by the volunteer after taking the medicine, are observed and noted very carefully. Afterwards all these symptoms are converted into reportorial language (integrated into existing rubrics or creation o a new rubric). The quality of each collected symptom is more important than the quantity of symptoms. Each proving result (symptom linked to a homeopathic medicine) has to be confirmed by other experiments and, later on, in the clinical practice. (Van Wassenhoven, p49)<sup>5</sup>

#### 1.3.9.2 At rational level

At pharmacology's rational level, in 1988, the INSERM's immunologist J. Benveniste claimed that IgE antibodies have an effect on certain cell type after being diluted by a factor of 10<sup>120</sup>. Results of this experiment were published by *Nature*<sup>14</sup>. The accompanying editorial of that time stated that "there [was] no objective explanation for these observations" ((*Nature* editorial, p 787)<sup>15</sup> cited in (Picart, p 11)<sup>16</sup>). "In addition, *Nature* undertook a unique step. It dispatched an investigative team to verify Benveniste's results. Even more unusual was the composition of the group" (Picart, p 11)<sup>16</sup>. So began what observers called later the "Ghostly Imprint" Saga<sup>16, 17</sup>. As detailed by (Picart, p 11)<sup>16</sup>, "the investigative team was composed of: I. John Maddox, the editor of *Nature*. 2. 'The Amazing' James Randi, a professional magician [...] whose 'presence was originally thought desirable in case the remarkable results reported had been produced by trickery'.[(Maddox, p 287)<sup>18</sup>] 3. Walter Stewart [...] whose chief concern in the past decade had been the detection of errors and inconsistencies in scientific literature, and the exposure of misconduct in science.<sup>19</sup> 4. A technician [...]".

After double blinding the experiment the effects could not be reproduced<sup>18</sup>. Nevertheless the first paper was read with interest by numerous homeopaths who interpreted Benveniste's claim as evidence for homeopathy and Nature's investigation as a farce. Twenty years after the J. Benveniste's "water memory" study, the European Central Council of Homeopaths (ECCH) recently informed his members that the new field of nanotechnology may provide the explanation as to what happens to the source materials of homeopathic medicines when they are potentised to dilutions beyond Avogadro's number<sup>20</sup>. Indeed prof. L. Montagnier, virologist and 2008 Nobel Prize winner for his pioneering research into HIV, intends to work in this field. For Prof. L. Montagnier, Benveniste was a modern Galileo, pioneering a new scientific movement at the crossroads of physics, biology and medicine. Now, Montagnier plans to work on electromagnetic waves that, he says, emanate from the highly diluted DNA of various pathogens and, as he argues, "[...]at 10-18 dilution, you can calculate that there is not a single molecule of DNA left. And yet we detect a signal. "21 . Once again, when scientists describe these ideas as "radical" and "shocking"21, homeopaths look forward to it with great hopes.

#### Key messages

- Homeopathy was developed by a physician at the end of the XVIII century partly as a critique of the heroic medicine of that time.
- Homeopathy is built on three key principles: the law of similars, the law of infinitesimals and a principle of globality.
- Homeopathy is practiced in Belgium by physicians from 1829 and more recently by lay homeopaths.
- The fluctuant popularity of homeopathy may be explained by scientific factors (the history of medicine) or by socio-economic factors (religion, homeopathic pharmaceutical industry and ecology).
- The quest of an "evidence-based homeopathy" is challenged by the EBM at both empirical and rational levels of the homeopathic pharmacology.

# 2 EFFICACY AND ADVERSE EVENTS

## 2.1 INTRODUCTION

We reviewed the scientific literature to document the efficacy of homeopathy. Because homeopathy involves an important number of conditions and proposed numerous remedies, we limited our review to systematic reviews. Therefore, only conditions for which we could find at least one systematic review were included. Moreover, we concentrated on reviews of randomised controlled trials. There is in the literature a lot of discussion on the plausibility of the mechanism through which it could work, but we did not focus on evidence for these mechanisms, neither did we cover topics such as utilisation in the population or social aspects. We did not focus on herbal remedies which are administered without following the homeopathic principles.

## 2.2 METHODS

We did a review of reviews and HTA reports, no additional search for primary studies was performed. The process of searching, evaluation and selecting studies was validated by a second person..

## 2.2.1 Databases and search terms

## 2.2.1.1 HTA reports:

For HTA reports, the CRD database was searched. Additionally, individual websites of HTA agencies were consulted (Table I).

Table I: individual HTA agencies

HTA agency	Website
SBU	http://www.sbu.se/en/
NICE	http://www.nice.org.uk/
DACEHTA	http://www.sst.dk/english/
MSAC	http://www.msac.gov.au/
MAS	http://www.health.gov.on.ca/
HAS	http://www.has-sante.fr/portail/jcms/j_5/accueil
AHRQ	http://www.ahrq.gov/
BCBS	http://www.bcbs.com/
AETSA	http://www.juntadeandalucia.es/
AATRM	http://www.gencat.cat/
CCOHTA	http://www.cadth.ca/index.php/en/home
ECRI	https://www.ecri.org/Pages/default.aspx
DIMDI	http://www.dimdi.de/static/de/index.html
IQWIG	http://www.iqwig.de/index.2.en.html

# 2.2.1.2 Systematic reviews

Systematic reviews and meta-analyses were searched in Medline, Embase and Cochrane Database of Systematic Reviews; Details of the search terms and the number of reports retrieved are presented for each database in annex.

## 2.2.2 Selection criteria

HTA (Health Technology Assessment) reports and systematic reviews were selected according to the following criteria:

P: patients suffering from any condition

I: homeopathy

C: any comparison: alternative intervention, placebo

O: patient relevant outcomes, such as mortality, morbidity, quality of life

D: HTA reports or systematic reviews

Exclusion criteria:

Narrative reviews, editorials, letters, primary studies, economic evaluations. Only publications in English, French, German, Dutch, Spanish or Portuguese were eligible for inclusion in the present report. Other languages were thus excluded. Search date of the review ending before the year 2000.

## 2.2.3 Quality assessment.

The quality of systematic reviews was assessed using the checklist developed by the Dutch Cochrane collaboration<sup>b</sup>. The following 8 items listed are: adequate research question, adequate literature search, adequate selection, adequate quality appraisal, adequate data-extraction, characteristics primary studies, adequate handling of clinical and statistical heterogeneity, correct statistical pooling. In the table they are numbered from I to 8.

In addition, when several systematic reviews were available on a specific sub-topic, the findings of the systematic review with the highest quality rating, most recent literature search or most comprehensive scope (in that order of importance) were reported and were compared with the results of the other systematic reviews on that topic

## 2.3 RESULTS

## 2.3.1 Reports and papers found

The number of papers found initially and selected in the end are given in figure one. Evaluation of the studies is given in table 1.

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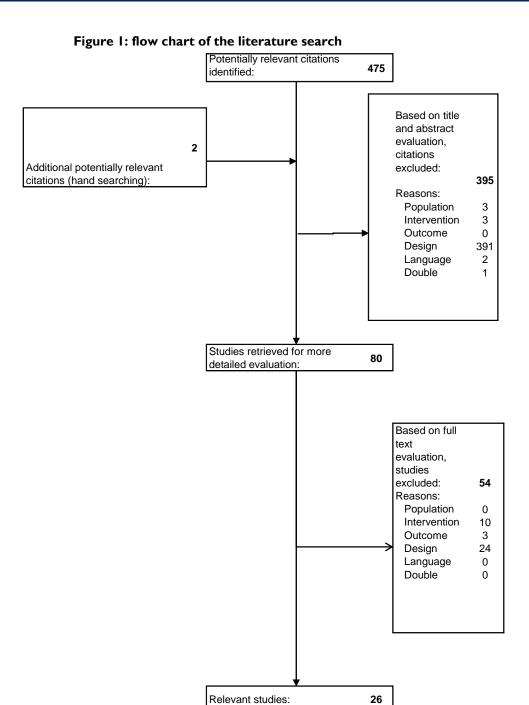


Table 1: Assessment of selected studies.

Author	Year	I	2	3	4	5	6	7	8	Total	Search date
Cooper KL <sup>22</sup>	2010	I	I	I	ı	I	ı	I	I	8	search date up to September 2010
Quinn F <sup>23</sup>	2006	I	I	I	ı	I	ı	I	I	8	search date up to 2005
Sarris J <sup>24</sup>	2010	I	I	I	ı	I	ı	I	I	8	search date up to 2010
Stevinson C <sup>25</sup>	2000	I	I	0	ı	I	ı	I	I	7	up to 2000
Smith CA <sup>26</sup>	2010	I	I	I	ı	I	ı	I	I	8	up to 2010
CRD <sup>27</sup>	2006	I	I	I	ı	I	ı	I	I	8	up to 2005
Ernst E <sup>28</sup>	2002	I	I	I	ı	I	ı	I	I	8	up to October 2000
Grabia S <sup>29</sup>	2003	I	I	I	ı	I	ı	I	I	8	up to 2002
McCarney R <sup>30</sup>	2004	I	I	I	ı	I	ı	I	I	8	up to March 2004
McCarney R <sup>31</sup>	2003	I	I	I	ı	I	ı	I	I	8	up to August 2003
Glazener C <sup>32</sup>	2005	I	I	I	I	I	I	I	I	8	up to November 2004
Mills E <sup>33</sup>	2005	I	I	I	ı	I	ı	I	I	8	up to 2003
Pilkington K <sup>34</sup>	2005	I	I	I	ı	I	ı	I	I	8	up to February 2004
Shang A <sup>35</sup>	2005	I	I	I	ı	I	ı	0	0	6	Pooling of very heterogeneous studies
Milazzo S <sup>36</sup>	2006	I	I	I	ı	I	ı	I	I	8	not reported
Passalacqua <sup>37</sup>	2006	I	I	I	ı	0	ı	I	I	7	up to September 2005
Pilkington K <sup>38</sup>	2006	I	I	I	ı	I	ı	I	I	8	up to August 2005
Robinson L <sup>39</sup>	2006	I	I	I	ı	I	ı	I	I	8	up to April 2004
Altunc U <sup>40</sup>	2007	I	I	I	ı	I	ı	I	I	8	up to 2006
Coulter MK <sup>41</sup>	2007	I	I	I	ı	I	ı	I	I	8	up to February 2006
Heirs M <sup>42</sup>	2007	I	I	I	ı	I	ı	I	I	8	up to 28 February 2006
Robinson L <sup>43</sup>	2007	I	I	I	ı	I	ı	I	I	8	u to March 2005
Langhorst J <sup>44</sup>	2008	I	I	I	ı	I	ı	I	I	8	up to June 2007
Baranowsky J <sup>45</sup>	2009	I	I	I	ı	I	ı	I	I	8	up to December 2006
Kassab S <sup>46</sup>	2009	I	I	I	ı	I	ı	I	I	8	up to November 2008
De Silva V <sup>47</sup>	2010	I	I	I	I	I	I	I	I	8	up to March 2009
Rada G <sup>48</sup>	2010	I	I	I	I	I	I	I	I	8	up to August 2008

# 2.3.2 Main findings on effects

### 2.3.2.1 Insomnia

Cooper et al $^{22$ ,  $^{49}$  found that the limited evidence available did not demonstrate a statistically significant effect of homeopathic medicines for insomnia treatment. Worth mentioning, existing 5 RCTs were of poor quality and were likely to have been underpowered. This was confirmed by a review by Sarris et al $^{24}$  who did not identify any RCT with a augmented Jadad scale<sup>c</sup> above 5/10.

# 2.3.2.2 Allergic rhinitis

Passalasqua et al<sup>37</sup>identified 10 RCT's on homeopathic treatment of allergic rhinitis and concluded that positive results were described in rhinitis with homeopathy in good-quality trials, but that an equal number of negative studies counterbalance the positive ones and that therefore it is not possible to provide evidence-based recommendations for the use of homeopathy to treat allergic rhinitis, and further randomized controlled trials are needed.

Augmented Jadad scale is a modification of the jaded scale, one of the scales used to assess the risk of bias in an RCT.<sup>50</sup>

#### 2.3.2.3 Low back pain

A review of Quinn et  $al^{23}$  found limited evidence (one high quality RCT) that homeopathic gel (Spiroflor SRL) and Cremor Capsici Compositus (CCC) are equally effective in the treatment of low back pain and that SRL has a lower risk of adverse effects than CCC. However, as stated in the original study there is no proof that CCC is effective in itself.

## 2.3.2.4 Third trimester cervical ripening or induction of labour

Smith et al<sup>51</sup>, based on 2 small trials involving 133 women, found no differences.

In any of the primary outcome measures described in this review. The quality of the trials was difficult to assess because of insufficient detail in the research papers, and the small sample sizes provides inadequate power.

# 2.3.2.5 Chronic fatigue

Bagnal et al<sup>52</sup> found that one RCT of good quality showed some evidence on one of 5 measures of fatigue and one in 5 measures of functional limitations. However, this should be viewed with caution because statistical significance was borderline with a considerable multiple testing problem as statistical significance was tested twice on 5 interdependent measures increasing the possibility of spuriously significant results.

#### 2.3.2.6 Dementia

McCarney et al<sup>31</sup> found no evidence (0 eligible studies) that homeopathic products have an effect on dementia and Robinson et al<sup>39</sup> found no evidence (0 eligible studies) of effect on wandering in dementia.

#### 2.3.2.7 Asthma

McCarney et al<sup>30</sup> found 5 trials of variable quality that did not demonstrate an effect and concluded that there is insufficient evidence to reliably assess the possible role of homeopathy in asthma.

#### 2.3.2.8 Enuresis

Glazener et al<sup>32</sup> found no evidence (0 studies) that homeopathy is effective for this condition.

## 2.3.2.9 Depression

Pilkington et al<sup>34</sup> found no evidence (no RCT's) for an effect in depression.

#### 2.3.2.10 Anxiety

Pilkington et al<sup>38</sup> found 7 RCT's but they report contradictory results, are underpowered or provide insufficient details on methodology.

## 2.3.2.11 Cancer related symptoms

Kassab et al<sup>46</sup> retrieved 8 studies, found that 2 studies of high quality showed statistically significant results: calendula oinment for the prevention of acute dermatitis during radiotherapy (Aria under the Curve Peto Odds ratio 0.42 [0.25, 0.68]) and Traumeel S mouthwash (a proprietary complex homeopathic medicine) in the treatment of chemotherapy-induced stomatitis (small study of 36 subjects stomatitis symptoms (WHO five point grading scale for mucositis Area under the curve): -14.24 [ -23.46, -5.02 ]. These interventions require further evaluation. There is no convincing evidence for the efficacy of other homeopathic medicines for adverse symptoms and skin reactions related to radiotherapy, nor for women with breast cancer. An older review Millazzo et al<sup>36</sup> found 6 studies of variable quality and reached similar conclusions.

## 2.3.2.12 Hot flushes in women with a history of breast cancer

Rada et al48 identified two RCT's of high quality that found no effect.

#### 2.3.2.13 Childhood ailments

Altunc et al<sup>40</sup> retrieved 16 studies on diverse childhood ailments, including Adenoid vegetation, ADHD, Asthma, Acute otitis, Conjunctivitis, Diarrhea, Postoperative pain agitation syndrome, URTI (Upper Respiratory Tract Infection) and Warts. They concluded that the evidence from rigorous clinical trials of any type of therapeutic or preventive intervention testing homeopathy for childhood and adolescence ailments is not convincing enough for recommendations in any condition.

#### 2.3.2.14 Attention Deficit and Hyperactivity Syndrome (ADHD)

Coulter et al <sup>41</sup> concluded that the forms of homeopathy evaluated to date do not suggest significant treatment effects for the global symptoms, core symptoms of inattention, hyperactivity or impulsivity, or related outcomes such as anxiety in Attention Deficit/Hyperactivity Disorder, based on a pooling of 4 eligible RCT's.

## 2.3.2.15 Fibromyalgia

Langhorst et al<sup>44</sup>, Baranowsky et al<sup>45</sup> and Da Silva et al all came to the conclusion in their reviews that there is no convincing evidence for an effect based on 3 small low quality RCT's.

## 2.3.2.16 HIV

Mills et al<sup>33</sup> found no evidence of an effect of homeopathy on CD4, body fat or symptom distress, identifying 2 RCT's with small sample size, concerns about the conduct and flaws in the analysis.

# 2.3.2.17 Chronic venous insufficiency

Ernst et al<sup>28</sup> found inconclusive evidence for an effect on venous filling time, leg volume and subjective symptoms based on one small trial, but needing replication.

## 2.3.2.18 Premenstrual symptoms

Stevinson et al<sup>25</sup> found no conclusive evidence, based on one underpowered RCT.

#### 2.3.3 Adverse effects

### 2.3.3.1 Aggravations and adverse effects

Homeopaths consider that their products may cause adverse effects and what they call homeopathic aggravations, an initial worsening of the symptoms. Dantas et al,<sup>53</sup>, based on 19 trials, concluded that homeopathic medicines in high dilutions, prescribed by trained professionals, are probably safe and unlikely to provoke severe adverse reactions. It is difficult to draw definite conclusions due to the low methodological quality of reports claiming possible adverse effects of homeopathic medicines. Grabia et al<sup>29</sup>, based on 25 trials, concluded that the data from placebo-controlled, double-blind RCTs of homeopathy mentioning the phenomenon of homeopathic aggravations do not provide support for the existence of aggravations.

## 2.3.3.2 Delayed diagnosis.

There is some anecdotal evidence for delayed diagnosis provided by Lim et al<sup>54</sup> describing 3 cases where homeopathy was involved. It is impossible however to evaluate the extent to which this is true or to give an estimation of the risk.

## 2.3.3.3 Vaccine uptake

There is conflicting evidence regarding the relationship between CAM (complementary & alternative medicine) use and vaccine uptake and the role of different CAM providers in this.

Jones et al found that, overall, there were no statistically significant odds ratios between use of any of the CAM therapies (including homeopathy) and receiving either flu, pneumococcal, or both vaccines but could not exclude it either<sup>55, 56</sup>. Zuzak et al found a significant relation between CAM use and vaccine refusal but found that this was mainly due to patient preferences and not induced by the CAM provider. He found that 43 % of users of homeopathy refused at least some basic vaccines but numbers specific for homeopathy were too small to find statistically significant results. Schonberger et al found that parental belief in homeopathy was a risk factor for non uptake of measles vaccination<sup>57</sup>. On the other hand, Stokley et al<sup>58</sup> found that CAM users had a higher vaccination coverage, even after adjusting for education and income level.

## 2.3.4 Discussion and conclusions

## 2.3.4.1 Main findings

We did not find compelling evidence that homeopathy works for any single condition. Shang et al<sup>59</sup> pooled 110 studies on homeopathy and came to the similar conclusion that the findings are compatible with the notion that the clinical effects of homeopathy are placebo effects. We did not include this study however because we consider it inappropriate to pool all treatments for all conditions, given the very diverse nature of the conditions that are treated, with a diverse range of symptoms in which placebo effects may play a role to a varying degree. The study was in contradiction with a study by Linde et al<sup>60</sup> doing a similar pooling and who found a pooled effect incompatible with placebo but where no proof for any single condition could be found.

We did not find evidence of side effects and only anecdotal evidence for patient delay caused by homeopaths. Also the relationship between CAM use and vaccine uptake seems complex and we did not find compelling evidence for the accusation that homeopaths have a harmful influence on the health seeking behavior of the patient. It is possible that homeopathy has a beneficial effect on drug consumption of the patient. More research on these issues would be useful here.

The quality of the reviews was variable but in general acceptable. A lot of the studies included in the reviews were of low quality. The well conducted large trials did not show an effect.

## 2.3.4.2 Placebo effect.

The question of placebo effects is complex and one can ask if making the distinction placebo-'real' effects is always that useful in practice.

The power of placebo effects and what is sometimes called 'enhanced placebo effects' is amongst others demonstrated for acupuncture and spinal manipulations<sup>61</sup>.

There is an increased attention in the medical literature for the usefulness and importance of placebo effects in clinical practice, and the role it plays when addressing pain, like its role in enhancing the effect of analgesics that have a proven effect beyond placebo, the role of provider knowledge and beliefs when administering pain killers.<sup>62</sup>.

Hróbjartsson A & Gøtzsche<sup>63</sup> did a meta-analysis and meta-regression to measure the effect of placebos and found that it was heterogeneous and that the effect depended on the type and credibility of the placebo. For instance, placebos involving a form of physical contact were more effective when used for pain relief.

However, measuring the effect of placebo is complicated due to differential drop out, poor acceptability of 'waiting list type' control groups and coping mechanism of suffering patients such as self medication or other forms of health seeking behavior.

## 2.3.4.3 Fundamental research on mechanisms.

We did not review the evidence for the mechanism that could explain an effect of highly diluted substances or the validity of the 'law of similars' (similia similibus curentur) as postulated by Hahnemann.

It is however fair to say that these notions, coming from an age dominated by the idea of 'vitalism', a doctrine postulating that the functions of a living organism are due to a vital principle distinct from biochemical reactions, discarded in mainstream science since the nineteenth century, lack plausibility. Some reviewers therefore question the need for additional trials, even well conducted ones, and contest that this is a good way to spend scarce resources available for research<sup>4</sup>.

## Key message

No convincing proof of efficacy exists for any condition for which a systemic review was available

# 3 USE OF HOMEOPATHY IN BELGIUM

## 3.1 SURVEY AMONG THE POPULATION

## 3.1.1 Objective

This section aims to measure the prevalence, utilisation and reasons for resorting to alternative medicines, and in particular to homeopathy, chiropractic, acupuncture and osteopathy.

#### 3.1.2 Methods

## 3.1.2.1 Organization

The Phonecom company conducted a telephone survey of a representative sample of 1999 adults in Belgium from December 2009 to January 2010 by using a CATI (Computer Assisted Telephone Interviewing) software.

## 3.1.2.2 Sampling

The source file used to survey home phone subscriptors was the CD-ROM infobel® 2009. A purely random selection was operated on the totality of the numbers available in Belgium. The people registered on the Robinson list were automatically excluded from this file, in accordance with the code of conduct of the BDMA (Belgian Direct Marketting Association). In order to survey the mobile phone holders, series of numbers of GSM were also randomly created and called.

On a total of 10.000 calls at the beginning, 1999 valid questionnaires were used for the analysis. Eligible people had to be older than 18.

### 3.1.2.3 Quota

A mixed method of quota sampling and stratified sampling was used by Phonecom. Quotas are presented in appendice with data from the National institute of statistics.

#### 3.1.2.4 Weighting

The sample distribution was similar to the census distribution for age, sex and region of the country (provinces). We weighted the data for education to match our sample to the distribution of the Belgian census.

# 3.1.2.5 Questionnaire

The questionnaire combines mainly questions resulting from two national surveys published in the JAMA and in the New England Journal of Medicine<sup>64, 65</sup>. Other more recent national survey questionnaires carried out in Japan<sup>66</sup>, in Australia<sup>67</sup> and in the United Kingdom<sup>68</sup> were also used. We asked respondents to report on:

- a. their demographic and health status,
- b. the frequency of use of alternative medicine (during lifetime and the preceding year),
- c. the medical reasons of their visits,
- d. the global attitudes towards the use of alternative medicine (alternative or complementary, depending on reimbursement),
- e. The characteristics of their unconventional therapist (diploma, accessibility, charges for visits and treatments),
- f. Satisfaction with conventional and unconventional therapist,
- g. Health representation (need for control).

Parents were asked similar questions about their children's health status, frequency of use and medical reasons.

## 3.1.2.6 Characteristics of the respondents

The sociodemographic characteristics of the survey population weighted for education are shown in appendix.

#### 3.1.2.7 Limitations

The fact that the survey in the general population was carried out by phone carries a risk of socio-economical or cultural bias because participants need to appear on a list of public numbers. More, only volunteers are participating. Nevertheless, the final sample is rather representative of the Belgian population and weightings were done to correct inadequacies.

## 3.1.3 The use of alternative medicines in general

In 2009, 33.7% of the interviewees had resorted to an alternative medicine during their lifetime (table I). Of the 1622 respondents that mentioned at least one medical problem during the twelve months prior to the survey, 14.9% had visited an alternative therapist during this period (table 2). This prevalence appears to be consistent with the results obtained during interview-based health surveys carried out by the Public Health Institute since 1997. The latest report available on the interview-based health survey conducted in 2008<sup>79</sup> indicates that there has been no increase over time in the use of providers of non-conventional therapies, except in Wallonia for osteopathy.

Just like the interview-based health survey, the survey indicates that during the 12 months prior to the survey the sub-groups of the population with the highest level of the education have consulted an alternative therapist to a higher extent (18.6%) than those with a lower level of education (10.6%) (table 3). Also, these therapies are most often used by middle-aged people (from 14.9% to 18.5% of people aged between 25 and 54 years) (table 4).

No significant difference was observed by gender: 14.3% of men and 15.5% of women have consulted and alternative therapist during the 12 months prior to the survey (table 5).

33.8% of the respondents stated that they did not know about alternative medicines; 25.7% said that they did not trust these medicines and 18.4% said that they did not need them. They were considered to be too expensive by 12.2% (table 6).

Osteopaths and homeopaths have been consulted twice as much as the other alternative therapists (table 7): 6.7% of respondents had visited an osteopath during the 12 months prior to the survey, 5.6% had consulted a homeopath, 2.7% an acupuncturist and 2.2% a chiropractor. Two-thirds of these patients had consulted them more than once during the past 12 months (table 7).

## 3.1.3.1 Medical reasons for using alternative medicines

The four medical reasons most often stated by consumers of alternative medicines during the past 12 months are: back problems (46.7%), neck pain (25.8%), fatigue (12.9%) and headaches (12.9%) (table 8).

Among those who gave only one medical reason for consulting an alternative therapist (166 out of 246 respondents), back problems were the main reason for consultation. This alone represented 70.7% of consultations of chiropractors, 45.8% of visits to acupuncturists, 47.4% for osteopaths and 31.4% for homeopaths (table 9).

## 3.1.3.2 The therapist-patient relationship

A large majority of the users of alternative medicines (87.4%) also consulted conventional doctors (table 10), most frequently for the same medical reason (table 11).

85.2% of all users of alternative medicines have total confidence in their therapist, whether it is a conventional or non-conventional doctor. Only 4.6% did not trust their conventional doctor but they did trust their non-conventional therapist (table 12). 91.1% of users stated that they understood the responses of the therapist to their questions, whether an allopath or alternative therapist. Problems of comprehension were not associated more with one or other medicine (conventional or alternative) (table 13).

In general, there was great satisfaction concerning the care received. Once again, patients that were dissatisfied with their conventional doctor also tended to be dissatisfied with their alternative therapist (table 14).

## 3.1.3.3 The price of a consultation

The last time that they had used an alternative therapist, 43.8% of patients had paid between 25 and 50 euros. More than a quarter of respondents (27.7%) did not remember the amount they had paid (table 15). The percentage that had been reimbursed by their insurance was 35.9% (table 16).

## 3.1.4 Use of homeopathy

For the 1612 respondents who reported at least one medical condition in the 12 months before the survey, 5,6% have visited an homeopath during this period (table 7). Most of them (73%) have visited an homeopath more than once in the past 12 months (table 17). The report from the 2008 Health Interview Survey indicates that there was a significant increase in use of homeopathy between 1997(4%) and 2001(6%)<sup>69</sup> followed by a stability period (6% in 2004) then a decrease in 2008 (4%).

For patients who reported only one medical condition in past 12 months, back problems are the most often cited medical reason (31,4%) to visit an homeopath, followed by neck pain (13,6%), allergy (11%) and fatigue (9,4%) (table 9). Among patients having visited an homeopath in past 12 months, 68% have also visited another provider of alternative medicine (table 18).

#### Key messages

- 33.7% of the interviewees had resorted to an alternative medicine during their lifetime
- 14.9% of respondents that mentioned at least one medical problem during the twelve months prior to the survey had visited an alternative therapist
- The four medical reasons are: back problems (46.7%), neck pain (25.8%), fatigue (12.9%) and headaches (12.9%)
- 5,6% of the population consulted an homeopath at least one time in the last 12 months
- 73% of homeopathy users consult several times per year
- Principal medical reasons to visit an homeopath are low back pain (31,4%), neck pain (13,6%), allergy (11%) and fatigue (9,4%)

### 3.2 CONSUMPTION OF HOMEOPATIC PRODUCTS

Apart from their efficacy is the prescription, price and use of homeopathic products an important issue.

## 3.2.1 Research question

There are at least two important questions:

- What is the total quantity of homeopathic drugs used in Belgium (according to age, sex or residence of the patient)?
- What is the repartition of homeopathic products amongst health care providers? We could asses if there is a negative correlation between the quantity of homeopathic products prescribed by the provider and the quantity of other (allopathic) drugs, in order to test the hypothesis that health care providers who prescribe more homeopathic products prescribe less (allopathic) drugs.

# 3.2.2 Availability of data

To address these issues we need a database of homeopathic products, similar to Pharmanet. Such a database does not exist.

The private company IMS (Intercontinental Marketing Services) has only partial data on customers of certain pharmacies. Moreover, we could not validate the method they use to extrapolate the data coming from their sample of 2810 pharmacies to estimate the quantity of homeopathic products used.

This absence of exhaustive and valid data has several reasons:

Firstly, part of the products are sold over the counter in pharmacies without a prescription, as a prescription is not compulsory. Secondly, part of these products are bought outside pharmacies and, according to the APB (Association Pharmaceutique Belge), consumer organizations such as Test-Achat or Nielsen do not have data on this issue either. Thirdly, even if it were possible to do a census on all pre-packed products delivered in pharmacies, there is no information on products prepared by the pharmacist themselves starting from raw materials, the rate in which they are transformed in end products and the stocks that eventually get lost. Finally, data from the IMS, the APB or even the sickness funds, which reimburse certain acts of non conventional health care providers, do not permit to establish any link between provider (if there), type and quantity of the product and the patient.

#### 3.2.3 Conclusion

It was not possible to analyze the data on the use of homeopathic products as the data are not available. So it is not possible for the moment to link the prescription of homeopathic products to the prescription of 'allopathic' drugs, nor to estimate the quantities used or by whom.

# 3.3 SOCIOLOGICAL ASPECTS: USAGE AND PRACTICE OF HOMEOPATHY IN BELGIUM TODAY

#### 3.3.1 Introduction

This chapter aims to provide an accurate description of the use and practice of homeopathy in Belgium, from a socio-anthropological perspective.

Homeopathy deserves special attention as it is the most commonly used form of non-conventional medicine in Belgium.

## 3.3.2 Objectives

The main objective of this section is to explore the social aspects of the use and practice of homeopathy from a perspective of understanding: we seek to understand, first, the medical rationale of regular and loyal homeopathy users and, second, the rationale of homeopathy practitioners.

## 3.3.3 Methodology

The original empirical material required for this section was collected using a **qualitative survey system of semi-structured interviews** with a small number of regular homeopathy users (n = 9) and practitioners (n = 10). The interviews with regular users were intended to ascertain, first, the reasons why users take homeopathic medicine and, second, their experience with this medicine.

The **interviews** were structured around a thematic interview guide inspired by international sociological literature. Each interview was then analysed in depth to form as comprehensive a view as possible of the respondents.

The **questionnaire for users** covered the following themes: the circumstances under which the user first used homeopathy; the frequency of and reasons for the user's current use of homeopathy; the role of homeopathy in the user's full range of health remedies; the user's interest in homeopathy; attitudes concerning the role of homeopathy in the healthcare system (price, access, etc.).

The **questionnaire for practitioners** covered the following themes: training followed; practice-related aspects (content and form of treatments); views concerning customers; collaboration with other health professionals; views concerning the current role of homeopathy in the healthcare system.

The interviews were carried out in the following steps: (1) contacting participants; (2) making appointments with those who agreed to take part in the survey; (3) at the start of the interview, providing them with prior information on the aims of the survey and requesting their signature of the informed consent form; (4) recording of the interview and note taking; (5) transcription of the interview.

The interviews were transcribed and analysed on the basis of a structuro-inductive thematic and conceptual analytical framework: the initial interviews with each category of respondent were analysed in detail in order to identify initial theoretical and analytical approaches, while the follow-up interviews were used to validate, refute or refine the hypothetical and analytical structure developed gradually as the material was examined. We then compared the answers to each of our questions.

A variety of channels were used to recruit participants: the social networks of researchers conducting the survey; expressions of interest in the questionnaire survey and lists of practitioners published by professional associations. A more or less equal number of users and practitioners were interviewed in the French- and Dutch-speaking parts of Belgium.

This exploratory empirical study was conducted on a non-representative sample of homeopathy users (n = 9) and practitioners (n = 10). It aims to provide further insight into the use and practice of homeopathy in Belgium. The conclusions we draw from the analysis of these interviews should therefore not be considered as general conclusions on this discipline.

## 3.3.4 Views of homeopaths

This first section aims to shed some light on the practice of homeopathy. We start by illustrating the reasons that prompted physicians and non-physicians to turn to homeopathy as their primary form of treatment and go on to describe the way in which they practice.

Our sample group comprises general practitioners, paediatricians, one immunotherapist and non-physicians. The fact that our sample group is composed chiefly of doctors is the result not of an initial choice but of our recruitment method (see methodology).

Table I: Sample group of homeopaths interviewed

	Language	Sex	Basic training	Unicist/complex	Place of practice
				homeopathy	(province)
I	FR	F	Medicine		Chastres (Walloon
					Brabant)
2	FR	М	Medicine		Rixensart (Walloon
					Brabant
3	FR	F	Medicine	Complex	Watermael (Brussels)
4	FR	М	Medicine		Gembloux (Namur)
5	FR	М	Medicine		Brussels
6	FL	М	Medicine	unicist	Brussels
7	FL	F	Language studies	unicist	Antwerp
8	FL	М	Doctor in	unicist	Ghent
			Homeopathy in Asia		
9	FL	F	Medicine	unicist	Flemish Brabant
10	FL	Σ	Medicine	clinical	East Flanders

FR: French-speaking; FL: Flemish-speaking; M: Male; F: Female

## 3.3.4.1 Some biographical details

The interviews with practitioners revealed that different avenues could lead physicians to favour the homeopathic approach in caring for their patients.

In the case of physicians, a first distinction must be drawn between those who have always practised homeopathy as their main treatment approach and those who started by practising conventional allopathic medicine but who, for various reasons, converted to homeopathy at a later date. This first distinction reveals two different ways of espousing the underlying conceptions of homeopathy.

### Homeopathy as a vocation

For some physicians, the practice of homeopathy can be seen as an expression of personal preference that prompted them to choose homeopathy from among the range of medical orientations open to them, in keeping with their views of what medicine should be. While some physicians are more attracted by a 'technicist' medicine of the body, others relate to a medicine oriented more towards comprehensive patient care. In some cases, this orientation may emerge as early as medical school:

"Pendant mes études, j'ai été choquée par le fait que l'on ne s'occupait que de l'organe, et très peu des gens. Les cours étaient donnés par des spécialistes, et non par des généralistes. Il n'y avait quasiment pas de place pour l'écoute de la personne. Je ne connaissais pas l'homéopathie, mais cela a tout de suite répondu à mes attentes, et je me suis rendue compte que pour moi, c'était ça..." (Practitioner 1)

For some practitioners, this vocation stems from their personal history and experience of homeopathic treatments:

"Il se fait que j'ai été soigné par homéopathie dès l'âge de 14 ans. Je n'avais pas de gros problèmes de santé, mais j'ai toujours été soigné par la suite par homéopathie. Ma mère m'emmenait voir un homéopathe à Ostende. À cette époque, je ne savais pas que j'allais devenir médecin, je n'ai fait mon choix qu'en rhétorique, mais j'étais déjà ouvert à l'homéopathie..." (Practitioner 2)

"Omdat ik als kind behandeld ben met homeopathie. Het is mijn geneesheerhomeopaat die mij gezegd heeft "ge moet eerst geneeskunde studeren en dan pas homeopathie." (Practitioner 6)

The 'vocationists' are impassioned by homeopathy, seeing it as a chance to practise a form of medicine that is always inspiring, exciting and satisfying. This passion for homeopathic medicine appears to stem from the fact that homeopathy requires practitioners to constantly doubt and question, especially as the discovery of the most appropriate remedy (similimum) is never guaranteed. So the practitioner is perpetually faced with real challenges with each and every patient, making homeopathy anything but routine.

"C'est une passion, je crois. On est toujours contents de faire ce que l'on fait, alors que quand on va à des réunions de médecins classiques, ces gens se plaignent de ne pas gagner assez, ils se plaignent de leur métier. J'ai toujours envie de leur dire que s'ils n'aiment pas leur métier, qu'ils fassent autre chose..." (Practitioner I)

#### Converts to homeopathy

Other practitioners report having practised for several years what they describe as "normal" or "conventional" medicine and later discovering homeopathy, which allowed them to 'rediscover' or at least to inject more excitement into their practice. These reports come across as real accounts of conversion, in the sense that homeopathy has made practitioners see medicine in a different light.

"Je faisais précisément de la recherche en épidémiologie et en néonatialité principalement, dont à cent lieues de l'homéopathie, et ce sont en fait des amis proches qui me parlaient de l'homéopathie, et moi je critiquais sans savoir ce que c'était, et puis je suis allée voir un peu plus loin, et je me suis dit que c'était intéressant, je me suis inscrite à un cours..." (Practitioner 3)

"Het is begonnen met onze kinderen. Die kleine kindjes en die waren constant ziek en vooral de kleinste die had een bronchiolitis. Die heeft op 6 maanden tijd een pneumonie gehad die tamelijk ernstig was. De pediater had toen gezegd "met die kleine gaat ge nog veel problemen hebben" en mijne man, die ook huisarts is, toevallig iets gevonden over homeopathie, daarover beginnen lezen. En dan hebben we onze kleine behandeld met homeopathie en dat was echt spectaculair." (Practitioner 9)

The career trajectory of these 'converts' is also reported by other practitioners and figures prominently in the rhetoric they use to justify their choice of practice to their colleagues and patients.

"Il arrive que des médecins classiques viennent aux cours d'homéopathie, pour voir ce que l'on fait, et pour avoir des arguments contre l'homéopathie, mais lorsqu'ils voient comment on travaille, ils sont surpris, puis reviennent, et après, cela devient les meilleurs homéopathes..." (Practitioner I)

"Wel, ik noem mij zelf nooit homeopaat, ik ben gewoon klassiek opgeleid kinderarts, maar ik gebruik alle middelen mogelijk om het kind te helpen. Dus maw hoe minder klassieke geneeskunde ik moet gebruiken, hoe minder medicatie, hoe contenter dat ik ben." (Practitioner 10)

In a medical context dominated by biomedicine or allopathic medicine, the words and actions of all homeopathy converts embody a certain endeavour to present homeopathy in a more acceptable light. In addition, the fact that 'conventional' doctors have converted to homeopathy is obviously an important tool for influencing others' perceptions.

#### Problems in training as a homeopathic doctor

All the Belgian practitioners whom we interviewed had been trained in Belgium. Those who had trained in homeopathy at medical school emphasised their teachers' scorn of homeopathy, as well as the personal sacrifices they had been forced to make to follow their vocation.

"Dat is een zware opleiding die er ge nog eens bij doet en dat is levenslang leren. Dat is heel tijdrovend. Die consultaties, ge kunt er maar I per dag doen. En financieel moet ge al serieuze bedragen gaan vragen, maar dat kunt ge niet in de praktijk." (Practitioner 9)

"Lorsque j'ai choisi de faire médecine, je savais déjà que je voulais devenir homéopathe, mais cela n'a pas été évident, surtout que l'on avait des cours de pharmacologie, où on nous disait que l'homéopathie c'était de la placébothérapie, on tapait dessus pendant vingt minutes et puis basta..." (Practitioner 2)

#### The essence of homeopathic practice

All the practitioners interviewed share the belief that homeopathy is a medicine more in keeping with their own views of what medicine and the medical profession should be.

"Avec l'homéopathie, on reconnaît que tout peut influencer l'ensemble, et si on tient compte de l'ensemble, on peut arriver à soigner les gens de manière beaucoup plus durable. C'est une médecine à long terme, très intéressante..." (Practitioner 3)

« Pour moi, c'est un vrai choix, parce que l'homéopathie correspond vraiment à la philosophie que j'ai de ce que devrait être un médecine, une médecine de santé, et non du symptôme que l'on veut réprimer... La façon d'aborder le malade est tellement différente..." (Practitioner 2)

They express no doubts that homeopathy is a medicine in its own right and a good substitute for conventional or allopathic medicine. In their view, homeopathy should not be reduced to mere placebo therapy and their experience largely corroborates their belief in its efficacy in inducing complete patient cure:

"Pour moi, et pour mes collègues, on arrive à de véritables guérisons, et pas seulement à la disparition du symptôme, mais le patient se sent mieux, se sent libéré de quelque chose... il n'est plus tout à fait le même..." (Practitioner 5)

Practitioners consider homeopathy to be more appropriate than allopathic medicine, particularly for health problems characterised as "chronic", which biomedicine admits it is powerless to cure completely because of the state of medical knowledge, for example<sup>70</sup>.

"Ca veut dire quoi, 'chronique', ça veut dire qu'ils ne peuvent pas les guérir, mais ne peuvent que leur donner des médicaments pour les soulager, alors que bien souvent, on peut guérir ces maladies par homéopathie..." (Practitioner 1)

- Practitioners who claim that they practise homeopathy as the result of a
   'vocation' justify their choice by a set of personal predispositions that
   prompted them to choose this form of medicine from among other possible
   medical orientations, in spite of certain social and contextual factors that
   could have influenced their choice
- By contrast, practitioner 'converts' have found homeopathy to be a more exciting and less routine medicine than the allopathic approach they formerly espoused.
- Both vocationists and converts emphasise the sacrifices they have had to make to train in a medicine that has many advantages over allopathic medicine but is rejected by faculties.

### 3.3.4.2 The different components of homeopathic treatments

#### **Anamnesis**

Homeopathic treatment always begins with an initial consultation, lasting up to 2.5 hours, to take the patient's case history (anamnesis), making it certainly one of the longest case-taking consultations of any type of medicine.

"Je fais toujours une anamnèse complète: j'interroge le patient sur ses antécédents médicaux, quels sont les problèmes, sur tout ce qu'un médecin doit savoir avant de commencer à soigner un patient, bref, j'ai une démarche proche de ce que j'ai appris en Faculté, mais je ne vais pas aboutir à un remède allopathique." (Practitioner 2)

However, consultations with paediatric and complex homeopaths<sup>d</sup> are shorter because case-taking is more limited.

"Hier duurt de gemiddelde consultatie 20 minuten. Het is wel zo, bij die gevallen, die meer uitzonderlijke gevallen van zwaar eczeem of zwaar astma, waar er echt dieper moet gekeken worden, dan is het meestal 40 tot 60 minuten." (Practitioner 10)

Homeopathic case-taking is structured in such a way as to induce patients to express a set of elements enabling the practitioner to form a rough picture of each patient and of their situation at the time of their consultation:

"L'important est de partir de la personne, de ses plaintes, et de son vécu, qui a quand même de l'importance : on ne tombe pas malade par hasard." (Practitioner I)

Case-taking consultations therefore allow patients plenty of opportunity to talk, in order to induce them to express what practitioners call their "vital sensations", or "inner experience". Meanwhile, the practitioner takes notes, working with his or her repertories on an open-book basis to seek overlaps between the symptoms identified and the remedies associated with them.

"Il faut être à l'écoute, et sans préjugés, sans émettre des hypothèses, être avec le patient tout le temps de la consultation, de manière à rester le plus neutre possible, tout en essayant d'aller au fond des choses..." (Practitioner 2)

See below: complex homeopaths use a combination of remedies, whereas unicists seek A SINGLE remedy.

The patient profile is established on the basis of his or her **symptoms**, which are clues that help the practitioner to gain a better understanding of patients. These symptoms may be physical (or local), psychological and general (sensitivity to the cold, sugar/salt, etc.). When establishing the patient's profile, practitioners rank each class of symptoms in grades of importance: some practitioners place great importance on general symptoms and others on physical symptoms.

"Il y a surtout les symptômes physiques, avec lesquels on ne peut pas se tromper. Si on a plusieurs symptômes concordants, y compris physiques, on est quand même plus sûr du résultat." (Practitioner I)

"J'essaie de me baser sur l'ensemble des symptômes mentaux et généraux : un patient est frileux ou a plus vite chaud, tous ces symptômes sont importants dans la recherche d'un remède, et les symptômes locaux, c'est une partie de son expression....." (Practitioner 4)

The practitioner is able to form an overall picture of the patient from the set of symptoms manifested by the patient, and to identify his or her 'profile' or 'terrain'. Obviously this helps to customise, or at least to give the impression of customising the treatment, which does not preclude the practitioner from making a 'conventional' diagnosis as any doctor would, but after carrying out a more in-depth examination.

"Ge kunt dat gemakkelijk samenvatten: er zijn geen ziektes, alleen maar zieken." (Practitioner 6)

The length of homeopathic consultations, especially the first one, calls for a specific organisation of the working day and significantly reduces the number of patients a practitioner can receive in one day.

"Je prévois dans mon agenda des tranches d'une heure et demie, ou de trois quarts d'heure par consultation. C'est sûr qu'on ne peut pas recevoir grand monde sur une journée, ce n'est pas très rentable financièrement, mais bon, je ne changerais pour rien au monde..." (Practitioner I)

"Om zo een hele dag homeopathie te doen, omdat ge heel goed naar de mensen moet luisteren. Er mag niks verloren gaan en dat is heel intensief. Ik zou dat niet een hele dag kunnen werken. Ge zit ook heel de dag op uw stoel, dus ge moet echt... Nee." (Practitioner 9)

#### The diagnosis

When making their diagnosis, homeopathic doctors do not differ much from 'conventional' doctors in their manner of proceeding:

"Quand on travaille, on doit faire un double diagnostic, je dirais : on fait un diagnostic de la maladie au sens où on l'entend en médecin, et puis je lui prescris un remède homéopathique ..." (Practitioner I)

The difference is that, when prescribing a remedy, homeopaths consider not only the symptom, such as a sore throat, but also the conditions of onset of the sore throat and the way in which the patient experiences it.

"Si un patient me demande ce qu'il doit prendre comme remède s'il a une angine, je dois lui expliquer que cela dépend s'il a mal à l'avant ou à l'arrière de la gorge, si l'angine a commencé à gauche ou à droite, s'il a mal ou non en avalant, si cela va mieux en buvant une boisson chaude ou froide, etc." (Practitioner 2)

It is chiefly at the level of patient care that the homeopathic approach differs so radically from the conventional approach.

In the case of non-physician homeopaths, patients usually came looking specifically for homeopathic treatment after receiving a diagnosis elsewhere.

"...meer dan 90% van de mensen die naar de homeopaat komen, hebben al een diagnose, dus dat heeft niks te maken met diagnose stellen." (Practitioner 8)

## Preventive approach

Its practitioners believe that homeopathy can enhance the patient's immune system. For this reason it is also used as a preventive approach.

"Dat is denk ik de basiswerking van homeopathie. (...) Voor hooikoorts absoluut, dat is hetgeen wat wij dagelijks doen. Voor grieptoestanden, voor oorontstekingen, voor recidiverende keelontstekingen, voor gevoeligheid voor longontstekingen, ... ja absoluut. Dat is juist de waarde van homeopathie, vind ik." (Practitioner 10)

#### From terrain to remedy

The homeopathic consultation is aimed at finding either the homeopathic remedy that matches all the symptoms manifested by the patient as a whole, or what is called the 'most appropriate remedy'. Each symptom and its specific manner of onset, of whatever type, provides elements that, once identified and compared, should point to the remedy (or remedies) matching all the elements identified during case-taking. The job of the practitioner is to find this remedy from a homeopathic repertory (paper-based or electronic) in an order or according to a method that varies from one practitioner to another. Classifications (remedies, plants, animals) can also be used. This search for a remedy is not based on medical diagnosis. The procedure used by the practitioner for finding this remedy is the second key plank of homeopathic treatment. It is also arbitrary to some extent, as there is no single path for arriving at this remedy. The remedy is a result of linking all the symptoms identified as significant, matching them and, most important of all, ascertaining their significance in the patient's personal history:

"Il faut chercher la signification du symptôme : pourquoi le patient a tel type de symptôme à tel moment... car si on soigne uniquement sur base du symptôme sans tenir compte du contexte, on passe à côté ..." (Practitioner I)

"Als een kinesist een behandeling doet, dan hangt dat er vanaf welke diagnose de arts heeft gesteld. Als wij een behandeling doen, eigenlijk hangt die behandeling helemaal niet af van de diagnose of van de diagnose die gesteld zou kunnen worden. Alleen de prognose natuurlijk. Wij baseren ons op andere dingen, meer op een heel algemeen beeld. Niet alleen de ziekte, maar ook de persoon zelf." (Practitioner 7)

The homeopathic remedy is meant to act on the person's terrain. Indeed, in homeopathy, the aim is to treat not the symptom but the patient's terrain, which the symptoms only reveal.

"Si on ne traite pas le terrain, le problème n'est pas résolu, mais risque de basculer vers un autre aspect. Rhumatisme et tuberculose, par example, font partie du même terrain tuberculinique, et si on ne soigne qu'un aspect, le problème peut se manifester autrement, et n'est donc pas résolu." (Practitioner I)

In homeopathy, the terrain is considered as a sort of genetic capital that is passed from one generation to the next.

"La maladie ne se transmet pas comme telle, mais il y a un 'terrain', qui peut être plus cancerinique ou tuberculinique, etc. On voit bien le terrain quand il y a par example dans une même famille différents types de maladie du même terrain, et si on ne soigne que les symptômes de cette maladie, on peut très bien voir ces gens basculer dans une autre facette du même terrain. Pour la médecine classique, ce sera deux maladies totalement différentes, mais pour nous ce sont différentes facettes d'un même terrain." (Practitioner I)

When identifying a remedy, the practitioner also takes into account certain behavioural traits in the patient, such as eating habits, which may undermine the treatment's efficacy.

"On essaie toujours de voir si le patient a un régime de vie correct, car sinon on donne des remèdes sur quelque chose qui est faux ..." (Practitioner I)

Practitioners claiming to be 'unicists' (or 'conventional' if they are non-physicians) endeavour to find the *similimum*, that is to say, the sole remedy that matches the symptoms of each patient, what they consider to be a 'deep' remedy affecting the innermost and most individual part of a patient's being, which is difficult to find.

"J'ai été formée à l'école belge qui est uniciste, c'est-à-dire qui préconise un remède pour une personne. Certains disent même qu'il y a un remède pour la vie, mais encore faut-il être sûr de l'avoir ..." (Practitioner I)

By contrast, complex homeopaths will give a combination of remedies depending on the different symptoms they take into account.

#### REMEDIES AND THE PHARMACIST

Patients usually leave the practitioner's office with a prescription for one or more remedies to buy at the pharmacy: a single remedy if the practitioner consulted is 'unicist' or 'classical' and several remedies if the practitioner practices 'clinical' or, 'complex' homeopathy.

#### Problem of remedy availability

Pharmacies do not keep all the homeopathic remedies in stock and very often need to order them on request. This can be seen as a problem where symptoms are acute. Patients may therefore be recommended to keep a minimum stock at home.

"Bijvoorbeeld vandaag belt iemand naar mij "ik heb koorts en die symptomen", dan zal ik aan hem zeggen "neem maar dat medicijn". Hij gaat naar de apotheek, maar ze hebben het niet. Dus bestellen ze het. Homeopatische middelen hebben ze meestal niet. De volgende dag gaat hij weer naar de apotheek, maar dan zijn symptomen anders. Dat is een groot probleem. Daarom vraag ik meestal aan mijn patiënten die goed op de hoogte zijn van homeopathie, "koop maar 10 of 12 algemene medicijnen van homeopathie en zet het in je medicijnkast". Dan kunnen ze naar mij bellen en dan kan ik zeggen wat ze moeten nemen." (Practitioner 8)

« C'est au niveau des remèdes que cela devient difficile, parce que les laboratoires doivent payer pour chaque remède, pour chaque dilution et pour chaque forme de remède, si bien que les remèdes qui sont peu prescrits vont disparaître et le prix des autres va augmenter. Tous les jours je reçois des coups de téléphone de pharmaciens qui me disent que ce remède là, on ne peut plus l'avoir, sous cette dilutions là, ou sous cette forme-là… » (practitioner I)

#### Collaboration between pharmacists and homeopaths

Pharmacists are not always trained in homeopathy and may interfere with the treatment prescribed by the homeopath.

"Of een kind met koorts dat ge iets voorschrijft en dat de apotheek zegt "maar ge gaat dat toch niet alleen met dat middel doen, dat gaat niet helpen?". Dat is soms vervelend, maar de mensen weten dat al "ik laat die doen"." (Practitioner 9)

However, collaboration is possible and can be trouble-free, especially if the pharmacist knows the practitioner.

#### Combination therapy

Some of the homeopathic practitioners interviewed do not offer their patients homeopathy alone. Sometimes they start by prescribing allopathic treatments for cases where homeopathy is not the most appropriate approach.

Some also combine homeopathy with other types of 'medicine', such as acupuncture (for acute pain for example) or herbal medicine.

"Je peux très bien donner un complément de phyto, par exemple, si cela me paraît utile... La phytothérapie n'est pas mon travail de base, mais je peux dans certains cas donner un petit complément." (Practitioner I)

"Wel fytotherapie, dat doe ik dan in combinatie. En ook wat orthomoleculaire geneeskunde, dat is ook wel heel interessant. Da's vooral voedingssuppelementen. Omdat ge zoveel tekorten ziet tegenwoordig, en ik vind dat ook wel een schone aanvulling op de homeopathie, omdat dat ook meer op het biochemische werkt." (Practitioner 9)

These few examples show that, for these practitioners, homeopathy is the basic therapeutic approach for their treatments but that they do not make it a hard and fast rule. Indeed, the homeopathic approach may be deemed unsuitable for certain clinical cases, for which practitioners prefer to use other means of treatment.

#### Follow-up consultations and treatment evaluation

The subsequent consultations tend to be shorter and less onerous for the patient. They aim to assess changes in the patient's status since the start of the treatment. Based on these factors, the practitioner may prescribe an alternative remedy or a different dilution of the same remedy.

The efficacy of the homeopathic remedy is evaluated chiefly on the basis of the 'law of cure' (a law that is considered as universal but is a central plank of homeopathy), which states that healing progresses from the centre of the body outwards, from the head downward and in reverse order of the symptoms, with a possible return to the previous symptom. The following interview excerpt illustrates how this law is involved in evaluating the treatment:

"Si par exemple quelqu'un qui a de l'asthme revient en disant que maintenant il a de l'eczéma à la cheville, pour nous c'est très bien... Par contre si quelqu'un vient pour de l'eczéma, mais depuis lors a des angoisses et ne dort plus, là on n'est pas contents..." (Practitioner I)

#### Telephone consultations

Although practitioners do offer telephone consultations, this is possible only with patients known to the therapist. The therapist will advise a particular remedy. However, if the symptoms do not disappear quickly, patients will be seen in consultation.

"lemand die ik niet gezien heb en die zegt aan telefoon, "ik ben aan het hoesten", dan weet ik niet wat het is. (...) Die moet ik dan zien, dan zeg ik "ofwel gaat ge bij uw behandelende geneesheer en komt ge met een diagnose naar mij ofwel komt ge direct naar mij". Maar een nieuwe doet ik nooit via telefoon. Het is in feite een service dat we geven aan de mensen die bij ons in behandeling zijn om hen correct op te volgen." (Practitioner 6)

#### Homeopathy hazards and side effects

In theory, the way in which homeopathy functions limits the hazards and side effects.

"Nee, ge kunt geen overdosis nemen." (Practitioner 10)

"Bij unitaire homeopathie niet echt een gevaar. Ik ben een unitaire homeopaat. De complexe is de mengeling, de mikmak en dan weet ge niet goed welk product nu werkt of niet. En bij unitaire weet ge het altijd, het werkt of het werkt niet." (Practitioner 6)

"Als ge natuurlijk een verkeerd middel neemt en van blijft nemen, kunt ge daar natuurlijk de nevenwerkingen van krijgen. (...) En soms bij heel gevoelige patiënten, maar dat zijn er niet veel, die reageren eigenlik heel snel met proevingssymptomen." (Practitioner 7)

However, practitioners should not exaggerate the effects they may expect.

"Als ge fanatiek zijt in de homeopathie en als ge denkt dat ge alles moet oplossen met de homeopathie, dat kan ook niet." (Practitioner 9)

# Homeopathic treatments are based on three highly specific procedures:

- very long case-taking consultations based on a predefined framework that allows the practitioner to establish the patient's terrain based on his or her physical and psychological, local and general symptoms;
- the prescription of one or more remedies corresponding to the set of symptoms and matching them with the use of homeopathic repertories;
- follow-up consultations to narrow down the search for the most appropriate remedy for each patient.

## 3.3.4.3 Homeopathy and allopathic medicine

#### From allopathic medicine to homeopathy

Even though homeopathy is practised by many physicians, many still consider it to be a form of medical heresy, prompting homeopathic practitioners to be even more cautious than their allopathic physician counterparts, knowing that they are more exposed than allopaths to various types of sanction. It is partly for these reasons that homeopathic physicians stress that they are first and foremost doctors and that the practice of homeopathy makes them more akin to specialists. Indeed, this seems to be the way they are perceived by some of their allopathic colleagues who sometimes refer to them patients suffering from chronic problems like eczema or asthma.

"Cela n'empêche que j'ai des amis généralistes ou spécialistes en médecine classique, qui sont quand même ouverts à une certaine forme de respect de la personne, et avec qui je collabore..." (Practitioner I)

"Ce n'est pas fréquent (que des allopathes réfèrent certains patients), mais cela arrive, pour de l'allergie, des choses comme ça... Alors, c'est comme si j'étais le spécialiste en homéopathie ..." (Practitioner 2)

Such forms of collaboration between homeopaths and conventional doctors does, of course, assume that homeopathic practitioners share a certain level of biomedical knowledge, as practitioners must be able to understand the diagnosis and the treatments administered to the patient whom they share, in a certain sense.

"Il faut être au courant, ne fut-ce qu'au point de vue du diagnostic, et pouvoir aussi discuter avec les autres médecins, on peut être plusieurs à avoir en charge un patient, plusieurs spécialistes, il faut pouvoir comprendre, être en collaboration pour le patient, c'est très important, donc il faut un minimum de connaissances générales." (Practitioner I)

This collaboration between homeopaths and allopaths could be advanced as a strong argument against the practice of homeopathy by non-physicians.

# From homeopathy to allopathic medicine or the 'limitations' of homeopathy

Sometimes the homeopathic approach comes against 'borderline' cases where physician homeopaths feel compelled to resort to allopathic medicine. In a sense, these cases reveal the limitations of homeopathic practice, which practitioners do not usually cross.

"Moi je dirais que l'on peut aider tout le monde... pas guérir tout le monde, mais aider, certainement, même les cas de cancer, car le fait de pouvoir lui donner un traitement homéopathique de fond va l'aider à mieux supporter ses traitements..." (Practitioner 2)

Sometimes the homeopathic treatment does not yield the expected results and the homeopath will turn to allopathic medicine.

"Bijvoorbeeld een zwaar astma, een zwaar eczeem. Die mensen staan meestal al onder zeer zware puffers en zware cortisonen. Meestal starten we dan een homeopatische behandeling op en dan kijken we hoe dat het gaat. En laten we zeggen, in 8 gevallen van de 10 kunt ge dan uiteindelijk toch wel ervoor zorgen dat ze duidelijk minder klassieke medicatie hebben of dat ze zelfs kunnen stoppen en dan gewoon met de homeopathie gaan verder doen. Maar we gaan niet te rap te radicaal afscheid nemen van de klassieke therapie." (Practitioner 10)

#### REFERRAL TO A SPECIALIST OR HOSPITALISATION

Where necessary, homeopaths refer their patients to a specialist or have them admitted to hospital, although in this case they will prescribe a remedy to help the patient to cope more easily with hospital treatments or to shorten their hospital stay.

"Als ik kan, dan stuur ik ze naar specialisten die ik ken en dan krijgt ge ook een eerlijk antwoord terug. Ze zetten dat ook in hun protocols dat de mensen een homeopatische behandeling volgen. Meer en meer, vooral bij de jongere generatie." (Practitioner 6)

"La plupart du temps, je m'en tire avec l'homéopathie, mais si je dois envoyer quelqu'un à l'hôpital, je le fais. Je donne alors un remède homéopathique avant qu'il n'y entre, et il faut dire qu'il en sort alors beaucoup plus rapidement qu'un autre malade..." (Practitioner I)

#### **LIFE-THREATENING EMERGENCIES**

Faced with a "life-threatening emergency" where it is important to act promptly using therapeutic methods that produce effects that are difficult to achieve with homeopathy, homeopaths do not hesitate to use allopathic medicine. This applies particularly to patients with high blood pressure, pneumonia, etc.

"Il peut m'arriver de prescrire ponctuellement un médicament classique à quelqu'un lorsqu'il y a une urgence médicale." (Practitioner I)

"Quand c'est vital, quand ça peut être dangereux, on ne traîne pas... C'est par exemple le cas de l'hypertension artérielle, pour laquelle il n'est pas évident d'obtenir une baisse de tension avec l'homéopathie. Je vais donc prescrire un antihypertenseur classique, qui prend alors place dans un traitement homéopathique plus large..." (Practitioner 2)

"Bij een pneumonie, mja dat lukt soms, maar je moet toch niet buiten je grenzen gaan. Ik vind toch wel dat je er als arts moet bij staan." (Practitioner 9)

"Pour une appendicite, par exemple, j'essaie de voir ce qui s'est passé, je lui donne un remède et je l'envoie ensuite à l'hôpital..." (Practitioner 4)

In such emergencies, practitioners do not renounce homeopathy altogether: they prescribe it **as a complementary therapy,** as a therapy of support, reassurance and assistance, in the symbolic and almost psychotherapeutic sense.

#### **CANCER TREATMENT**

Homeopathic practitioners do not feel "entitled" to treat cancer patients, at least in the first instance and as the primary approach.

"Il y a bien sûr des cas-limites, que l'on réfère à un spécialiste compétent. Un cancer, par exemple, je n'ai pas le droit de le soigner par homéopathie, n'empêche que la plupart du temps, on peut quand même les aider, et on pourrait aussi les soigner, on connaît tous des cas de cancers guéris par homéopathie uniquement." (Practitioner I)

"Je travaille par exemple avec des patients qui ont des cancers. Je n'arrête absolument pas les traitements, au contraire, je collabore, mais moi j'aide les gens à mieux supporter leurs chimiothérapies." (Practitioner I)

"Bij kanker, die moet geopereerd worden of chemo krijgen of straling, maar wat ik dan doe, is de mensen ondersteunen. (...) Dat zijn trouwens zaken die ik nooit alleen behandel, maar altijd samen met de specialist." (Practitioner 6)

These examples show that homeopathy may be an alternative and/or complementary medicine, depending on the cases and the diseases involved.

"Lorsque par exemple quelqu'un est malmené par d'autres médicaments, cette personne vient chez moi pour être aidée à l'égard des traitements très lourds qu'elle subit..." (Practitioner I)

The use of homeopathy as either an alternative or complementary medicine seems to be related to the boundaries that physician practitioners are careful not to cross because of their therapeutic responsibility towards patients.

#### **VIEWS ON VACCINATION**

A number of homeopaths interviewed on the subject, both physicians and non-physicians, voiced reservations about the merits of vaccination, particularly among children. These reservations applied to all vaccines or only to the more 'commercial' ones, such as rotavirus and chicken pox.

"Zeker als kinderarts ben ik het daar niet meer eens [tegen de vaccinatie]. Laten we zeggen, vaccinatie in bepaalde gevallen zijn goed, in vele gevallen is dat ook niet goed. Bijvoorbeeld rota-vaccin, dat is geen levensbedreigende ziekte, varicella." (Practitioner 10)

Some provide their patients with a vaccination 'damage-prevention' leaflet.

"Dat betekent voornamelijk voor mezelf dat ik daar tegen ben, maar naar de patiënten toe wil dat zeggen... dat ik vind dat ze zich van de 2 kanten moeten laten informeren (...)" (Practitioner 7)

They accuse vaccination of being artificial (inoculation by injection) and causing premature exposure to pathogens. They also stress the risk of side effects, such as the onset of autoimmune diseases in adulthood. They believe that homeopathy is enough to boost the immunity of young patients and avoids the use of vaccination. Should disease occur, then homeopathy can be used to treat the patient.

"(...) baby'tjes van 3 maanden krijgen dan 9 vaccinaties (...) dus dat lichaam is daar niet klaar voor. En dat lichaam moet dus tegen die 9 ziektes antistoffen aanmaken en dan ziet ge pas dat ze ziek worden na vaccinatie. Wat ik wel doe, is ze homeopathie bijgeven. Dus als ze echt willen vaccineren, dan... Maar ik ga het niet zeggen dat ze niet mogen vaccineren, want dat is in deze tijd moeilijk." (Practitioner 9)

- The dialogue between homeopathic and allopathic doctors requires a sharing of medical knowledge that argues for restricting homeopathic practice to medically trained practitioners.
- The homeopathic approach has certain therapeutic and ethical 'limitations'.
- Homeopathy is seen as inappropriate for dealing with medical emergencies
  or life-threatening situations, or certain diseases such as cancer, at least as
  the primary therapy. In such situations, homeopathy is nevertheless
  prescribed as a support therapy alongside allopathic treatments.
- Therapists have differing views on the usefulness of vaccines. However, some put across an 'anti-vaccine' message.

# 3.3.4.4 Non-physician homeopaths

#### Physician-homeopaths' views concerning non-physician homeopaths

Some physician homeopaths do not oppose the practice of homeopathy by non-physicians.

"Maar in principe, als we alleen naar de patiënt kijken en die kan geholpen worden door een niet-arts die een zeer goede homeopaat is, als die mens geholpen is, waarom niet?" (Practitioner 10)

However, physicians do fear that non-physicians might miss something.

"De kans dat een niet-arts iets mist, is veel groter dan dat natuurlijk een artshomeopaat iets gaat missen. Een arts-homeopaat gaat evenveel missen als een klassieke arts. Het zou zo moeten zijn." (Practitioner 10)

#### Professional practice

It is difficult for anyone not trained as a doctor to work full time as a homeopath. First, they are less well known and, second, they are not permitted to issue a medical certificate of incapacity for work, meaning that patients are forced to go through a doctor too.

Ten eerste is het redelijk onbekend, ten tweede zijn veel mensen bij een arts. En als ze ziek zijn hebben ze een briefje nodig en moeten ze naar een arts gaan. Als mensen mij bellen van oei ik ben nu ziek, ik heb een briefje nodig. Dan moet ik zeggen "sorry, ik mag u geen briefje schrijven, u mag altijd naar mij komen maar gaat u ook naar een huisarts of naar een arts-homeopaat". (Practitioner 7)

#### Role of non-physicians in the healthcare system

Communication between homeopaths and the medical community is not easy, especially for legal reasons of confidentiality (see also the legal section).

"Maar als ik weet dat een patiënt die bij een huisarts gaat die ik goed ken, eigenlijk wettelijk gezien mag ik niet naar die huisarts bellen om iets te vragen. Ik kan alleen aan de patiënt zeggen "kunt ge niet een briefje vragen aan uw dokter dat ik mag lezen?"." (Practitioner 7)

However, according to the practitioners interviewed, it is theoretically possible for them to work together.

"Wij zien dat veel breder dan enkel geneeskunde. Plus dat we ook de medische diagnose meestal niet nodig hebben om te behandelen. Natuurlijk kan dat helpen voor de prognose of zo en om soms te zeggen dat ge met die ontstoken blindedarm naar het ziekenhuis moet, maar om te behandelen hebt ge die niet nodig. Dus dat zou perfect naast elkaar kunnen bestaan en kunnen samenwerken." (Practitioner 7)

"Dus in mijn geval zou ik eerst de arts een diagnose laten stellen en daarna homeopathie proberen. En dat is de beste weg." (Practitioner 8)

# 3.3.5 The experience of users

#### 3.3.5.1 Brief introduction to homeopathy users

The majority of the users whom we interviewed for this study are women, mothers who, for the past five years or more, have consulted a homeopathic doctor on a regular basis, both for themselves and for their children. One man participated in the interviews. Some have been using homeopathy since childhood and others as the result of a specific event that prompted them to switch to homeopathy and then to adopt it as their regular medicine. As we shall see, their espousal of homeopathy is often the result of meeting a practitioner and their positive experience of the practitioner's care. The fact that our sample group comprises mainly women in a specific age group, three of whom are of foreign extraction, is obviously not with relevance to the analysis we make of their experience with homeopathy, given that women are more affected than men by such aspects as childbirth, childcare and home nursing in general<sup>71</sup>. Remember that our description is not intended to be representative of the experience of all users, but rather to suggest elements that might help us to understand this experience. In addition, the composition of our 'sample' does reflect a certain reality because most homeopathy users are women in the age group represented herein.

Table 2: Users of homeopathy

Users	Language	Sex	Age group	Profession	Place of residence (province)
I	FR	F	30–40	Social worker	Namur
2	FR	F	50–60	Teacher	Mons
3	FR	F	30–40	Actress	Brussels
4	FR	F	30–40		Brussels
5	FR	F	30–40	Headmistress	Walloon Brabant
6	NL	F	30-40	Social worker	East Flanders
7	NL	F	30-40	Employee	Antwerp
8	NL	F	50-60	Employee	Antwerp
9	NL	М	70-80	Retired	Limburg

FR: French-speaking; FL: Flemish-speaking; M: Male; F: Female

## 3.3.5.2 The circumstances of homeopathy use

As the decision to use homeopathy forms part of a set of motivations stemming from a variety of sources, it is difficult for us to make generalisations from the few cases analysed herein. We shall try to explain these circumstances just as users described them to us, and on the basis of selected excerpts from the interviews.

"Vers mes dix-huit ans, j'ai eu énormément de migraines... Je suis allée du côté de la médecine conventionnelle, et là on m'a donné des médicaments, mais qui ne me soignaient pas, qui me soulageaient au niveau de la douleur. Quand je suis venue en Belgique, vers vingt et un an, j'ai rencontré un homéopathe, parce que la maman d'un copain m'en avait parlé..." (User 4)

"Ik weet zeker dat ik toen gezegd heb dat ik altijd koude voeten had. Ik herinner mij als ik op de lagere school zat, van toen al had ik koude voeten, altijd. Ik heb dat gezegd tegen de homeopaat en die heeft mij een pilletje gegeven en ik heb nooit meer koude voeten gehad." (User 9)

"Je consulte toujours le même homéopathe depuis que je suis toute petite. Je pense que je me soigne par homéopathie depuis l'âge de trois ans... Et pour mon fils, j'ai choisi une pédiatre homéopathe. Elle m'a été recommandée par l'hôpital où est né mon fils..." (User 5)

In general, user's motivations seem to be structured by a search not for a more effective medicine but for a medicine that differs from conventional medicine: a more holistic, more natural and more accessible medicine that is not confined to treating the symptom, for instance. We can identify different circumstances under which these motivations arise.

According to users' accounts, homeopathy is a **more appropriate form of medicine for children.** Moreover, the fact that some maternity units advise young mothers to consult a homeopathic paediatrician seems to demonstrate a certain recognition for paediatric homeopathy.

In many cases, the decision to call upon the services of a homeopath is motivated by the desire to avoid treating children with antibiotics, which are considered as real poison remedies. Fear of the iatrogenic effects of allopathic treatments is another factor prompting the use of a form of medicine, which, even when ineffective, at least does not harm a child's body.

"Et puis, j'ai eu des enfants, et à la maternité, on m'a demandé si je voulais être suivie par un homéopathe, et j'ai dit oui pour les enfants... Ils sont si souvent malades que je n'allais pas à chaque fois leur donner des antibios, au moindre petit rhume..." (User 4)

"Dans mon idée, le recours à l'homéopathie, c'était vraiment pour les enfants, pour éviter dans la mesure du possible d'affaiblir leur organisme, et de les soigner de la manière la plus naturelle possible." (User I)

The thinking on **vaccination** follows the same rationale.

"Het was ook meer, de bewaarmiddelen van haar vaccins waren nog niet volledig afgebroken, daardoor had ze een verminderde weerstand en daardoor kwam die intolerantie. Het kringske was eigenlijk rond. Ik heb dat aan de homeopaat gezegd dat we nu daar mee bezig zijn." (User 6)

The use of homeopathy may be prompted by the onset of **certain chronic health problems for which no solutions have been found in conventional medicine**. This is particularly the case with the recurrent migraines that afflicted one user from the age of eighteen, or when allergies appear suddenly in a child.

"Il n'y a pas longtemps de cela, la petite avait des allergies alimentaires. Je suis allée voir directement un allergologue traditionnel, qui a fait tous les tests possibles, et il m'a finalement donné une crème à la cortisone, en disant que cela ferait certainement l'affaire... (...) et puis une amie m'a parlé d'un homéopathe spécialisé pour les allergies. Je suis allé le voir. Il m'a demandé quelles étaient les habitudes de l'enfant, qu'est-ce qu'elle mangeait, etc., et puis, il m'a prescrit un remède qui n'a pas fait tout de suite de l'effet, mais deux semaines après, elle n'avait plus rien, et cela fait plus d'un an et demi qu'elle n'a plus rien.... Donc je pense qu'il y a des problèmes pour lesquels la médecine ne peut rien faire..." (User 4)

"Mijn vrouw die hoestte heel veel en we zijn naar de huisarts geweest. Die heeft haar onderzocht en die zegt "ge hebt een chronische bronchitis, ge zult daarmee moeten leren leven". Tja.. de andere dag zijn we naar de homeopaat gegaan, ze heeft een pilletje genomen en ze heeft nooit meer gehoest." (User 9)

Homeopathy has a 'good reputation' for its efficacy in treating chronic problems like migraine, allergies, asthma and eczema, which are quite common. This explains why, when such problems arise, and especially where they persist, friends and relatives will readily recommend homeopathy.

"Mijn zoon heeft veel last van zijn neus, die snurkt en iedere winter verkoudheden. Met aerosol, antibiotica verschillende keren op een winter. Wij vonden dat geen goede toestand, maar wat kunt ge doen? En vanaf het moment dat wij naar de homeopaat gegaan zijn, is dat eigenlijk gedaan. Hij heeft geen aerosol moeten gebruiken of antibiotica moeten nemen." (User 7)

The family background can also prove decisive in the use of homeopathic care. Indeed, some users report having been treated with homeopathy "since childhood", which reflects not only a form of familial transmission but also corresponds to the type of medicine desired and valued within the family setting. Thus they use a homeopathic doctor "out of habit", because this is part of the family culture.

"Je suis allée chez cet homéopathe parce que mes parents y étaient allés et m'y emmenaient aussi. Il les a aidés pour des problèmes très importants, que d'autres n'avaient pas pu régler. J'ai donc grandi dans la confiance en ses traitements et j'ai donc logiquement continué chez lui, qui me connaît particulièrement bien, étant donné l'âge où j'ai commencé à le voir" (User 5)

In many cases the use of homeopathy therefore appears to be shared by all household members and sometimes, but not always, by members of the extended family.

"Ma mère, mon père (après moi), ma fille, ma sœur et ses enfants consultent mon homéopathe." (User 2)

"On est tous chez le même homéopathe... Mon mari avait des allergies, il s'est fait traiter, et puis voilà..." (User 4)

"Ik heb familie, een jongen van 27 en die heeft chronisch vermoeidheidssyndroom en die zijn al naar 10-20 dokters geweest en dat heeft allemaal niet geholpen. Ik denk, moesten ze onmiddellijk naar de homeopaat zijn geweest, dat zou genezen zijn. Mijn vrouw is ook in dat geval geweest. Ze had zona en ik vertel aan mijn homeopaat "ze wil niet". Een tijdje later heeft ze het heel erg gehad en ze heeft dan elektrotherapie gekregen en later heb ik gelezen dat dat heel slecht is, maarja de dokter zegt dat dat heel goed is en de kinesist ook. Maar zij is daar nooit vanaf geraakt en ze heeft dat 7 jaar lang gehad. En iedere morgen zat ze te wenen van de pijn. Maar ik denk, als ze naar de homeopaat was geweest... maar ik denk dat ze te lang heeft gewacht." (User 9)

The decision to be treated using homeopathy usually forms part of a set of decisions that might be summarised as a series of rejections or even as breaking away from conventional medicine. The choice of homeopathy is clearly motivated by a demand for a more "natural" medicine, in reaction to the side effects of allopathic drugs.

## 3.3.5.3 Homeopathy or allopathy?

Users visit their homeopath just as they would a conventional general practitioner, that is to say, they consult the homeopath on all the ordinary problems that arise throughout the year, according to the seasons and circumstances. The comments of User I illustrate this organisation of homeopathy use (and its perceived powers):

"Aussi bien moi que mes enfants, on se fait soigner par homéopathie pour des choses relativement bénignes, pour les petits bobos que l'on peut avoir tout au long de l'année: pour un rhume de foins, une angine, une pharyngite, une diarrhée, une gastro, des petits boutons sur le corps... là on s'adresse à l'homéopathe, uniquement, et cela marche très bien... Mais il n'y a jamais rien eu de grave..." (User I)

"Ik heb een huisarts, bijvoorbeeld voor mijn hart en bloeddruk. Ik moet pillen nemen tegen de bloeddruk en hartritmestoornissen. Ik heb dat voorgelegd aan de homeopaat en die heeft gezegd "sommige medicamenten moet ge volledig nemen zoals de huisarts heeft gezegd, maar andere kunt ge wat minder innemen". In plaats van alle dagen, om de 2 of 3 dagen. Hij heeft ook gezegd "die medicamenten van de huisarts moet ge alle dagen nemen". Dat is het voordeel dat de homeopaat ook een gewone arts is." (User 9)

It is only when things become complicated that users consult an allopathic physician. Indeed, they make a distinction between ordinary ailments that they personally consider to come within the jurisdiction of homeopathy and problems they themselves describe as "more serious" or requiring "mechanical" intervention, for which they prefer to use conventional medicine.

"La médecine 'classique' est vraiment intéressante pour les actes plus 'mécaniques' et pour des maladies plus graves aussi, je dirais..." (User I)

"Ma plus petite fille avait une inversion des vaisseaux cardiaques à la naissance, ce qui veut dire intervention chirurgicale directe, sans quoi je n'aurais pas de petite fille. Maintenant, elle est soignée par homéopathie, les deux sont toujours liées, elle aura toujours une relation avec l'hôpital..." (User 4)

The decision to use a homeopath rather than a conventional therapist is always a matter of users weighing up the situation, depending on their perception of the gravity of the problem and their experience of the different treatment alternatives.

- The decision to use homeopathy is set in the context of a variety of circumstances prompting users to switch from conventional medicine to a different type of medicine.
- Homeopathy is described as an ideal choice for treating children.
- Another reason for turning to a homeopath is the onset of certain chronic health problems for which no solutions have been found in conventional medicine.
- In some cases the family background and habits, which implies some form of transmission of healthcare choices, play a decisive role in the use of homeopathy.
- Users make a distinction between ordinary ailments, which they refer to their homeopath, and problems that are "more serious" or requiring mechanical intervention, for which they prefer to use conventional medicine.

## 3.3.5.4 Users' experience of treatments

From the users' perspective, homeopathic treatments are just the tip of the homeopathic iceberg in the sense that, in general, neither the philosophy nor the nosology of homeopathy is explained. Patients have access to homeopathy only via the words, actions and objects comprising the treatments, which are underpinned by certain fundamental principles of homeopathy, including customisation of treatment, pathogenesis of the terrain, etc., but 'translated' into words and actual practices by the practitioners whom they consult.

In other words, users have a **triple experience** of homeopathic medicine: (I) the experience of a relationship with a homeopath; (2) the experience of an original 'therapeutic system' comprising a model of organisation of consultations, a vocabulary, a concept of health and illness, remedies with which 'natural' virtues and specific methods of use are associated and (3) the observation and perception of the evolution of a disease, ailment or 'problem' treated in a specific way.

#### 1) The homeopathic relationship does not preclude allopathy

Users' 'relationship' with 'their' homeopath goes beyond the scope of the confidential medical relationship between physician and individual patient (colloque singulier) in the consultations upon which the homeopathic treatment focuses. Users do not tend to perceive their homeopath as a therapist whom they consult for an ad hoc problem, but rather as a kind of guarantor of their health who favours a natural and preventive approach. This concept of the homeopathic practitioner is expressed in part by the prescription of preventive treatments, which are an important part of the homeopathic arsenal. The homeopath's role is not reduced to that of repairer of the body, but is closer to that of a coach who prepares his or her patient to face the winter with a preventive treatment against influenza or who prevents hay fever just before spring.

"Il nous propose aussi des traitements de fond pour les enfants avant l'hiver, pour traverser l'hiver sans soucis... et pour moi aussi, un traitement de fond pour le rhume des foins.." (User I)

"Je consulte mon médecin traitant (homéopathe) au moins deux fois par an : en automne et au printemps, plus si je ne vais pas bien..." (User 2)

A number of users therefore **consider it important for their homeopath to be a trained doctor**, given that they refer to the homeopath problems of which they tend to ignore the severity and which they trust the homeopath to treat in an informed manner. They therefore expect their homeopath to discriminate between problems for which homeopathy is appropriate and sufficient, and "serious" or "mechanical" problems for which an allopathic prescription is required. So, users expect the homeopathic prescription to draw the line at urgent, difficult and organic cases <sup>72</sup>. Therefore, underpinning their use of homeopathy, users are expressing a rationale of discrimination, calling for a better match between ends and means.

"Notre médecin de famille est homéopathe et s'adresse à nous en tant qu'homéopathe. Cela a quelque chose de rassurant pour moi de savoir qu'il est quand même médecin généraliste en cas de problème plus grave, ou bien si l'homéopathie rencontre une limite..." (User I)

"Zou dus nooit naar een homeopaat gaan die geen dokter is. Dan heb ik daar geen vertrouwen in. Ik vind dat wel belangrijk dat ze arts is." (User 8)

"Ce qui est important pour moi, c'est que mon médecin, comme la pédiatre de mon fils, ont tous les deux fait des études de médecine. Ils peuvent en cas de problème plus grave, prescrire un autre médicament. Pour mon fils, je voulais quelqu'un qui puisse détecter quand il s'agit de quelque chose de grave (pneumonie, méningite...) et qui puisse prendre les mesures adéquates le cas échéant..." (User 5)

For ailments posing no real threat, users appreciate receiving non-toxic homeopathic treatment. For problems where allopathic medicine is required, they clearly prefer to receive allopathic treatment, possibly supplemented by homeopathic treatment.

"Mon aîné a eu une pneumonie, et mon homéopathe a dit que c'était trop loin, qu'un remède ne suffira pas, et il a prescrit un antibiotique. Je peux parfaitement comprendre que pour un cas extrême, un cas d'extrême urgence, qu'il faille en arriver là, mais je pense que pour tous les petits bobos, toutes les petites maladies des enfants, je pense que l'on pourrait se satisfaire de moins d'antibiotiques..." (User 4)

In no way do users want their homeopath to stick strictly to prescribing homeopathy but want the homeopath to use it to its limits. Thus they are delegating to the homeopath the responsibility for judging the boundary between homeopathy and allopathy. Moreover, users' trust in the homeopath is based on this ability to judge.

"J'ai plus confiance en quelqu'un qui va avoir une vision globale des choses que dans une analyse locale du problème" (User 5)

Obviously this is a strong argument against the practice of homeopathy by non-physicians, given that users consulting a homeopathic doctor are first and foremost consulting a physician who can prescribe either homeopathy or allopathy, depending on the circumstances.

The quality of the relationship and the way in which a homeopathic consultation takes place is a crucial element for users, with some going so far as to say that, in certain cases, they consider the consultation to be more important than the remedy.

"J'avoue que je pense parfois que la séance chez le médecin a plus d'impact que les granules qu'il me prescrit. Mais peu importe finalement, c'est d'obtenir un résultat, que je n'ai pas quand je consulte quelqu'un d'autre" (User 5)

- Users may perceive the homeopath as a guarantor of their health over the seasons more than as a repairer of the body whom they consult when problems arise.
- Users view homeopathy as a different type of medicine, but as a medicine nonetheless. They consider it important for their practitioner to have medical training and a good knowledge of the human body.
- Users consulting a homeopathic doctor do not expect him or her to prescribe homeopathy at any cost but to discriminate between problems for which homeopathy is or is not sufficient.
- Users attach just as much importance to the consultation with their homeopath as to the remedies they receive.

### 2) Perception of the components of the homeopathic system

**The initial consultation** gave interviewed users the impression that they had been questioned about various aspects of their lives and so had been cared for "holistically":

"Je garde l'impression d'avoir été prise en charge de façon intégrale. Le médecin a posé des questions à propos de mon parcours de vie, de mes sentiments, mes émotions, mon dossier médical, ma condition physique, mon entourage familial, ma situation professionnelle, etc." (User 2)

What they remember most is **the questions** they were asked during the case-taking consultation, some of which they felt bore little direct relationship with their complaints or health:

"Elle posait des questions qui n'étaient pas strictement liées au symptôme ou au corps : est-ce que je préfère manger salé ou sucré, est-ce que je me lève tôt ou tard, est-ce que je suis frileuse, etc." (User I)

Food plays an important role in the aspects examined by practitioners.

"Elle insiste énormément sur les choix alimentaires, elle est très sensible à cela, avec parfois quelque chose d'assez rigide..." (User I)

Users generally see these questions about many aspects of their lives as intended to identify the patient's personality and are the first element of what users perceive as a holistic approach.

So, from the first consultation, the patient experiences a medicine for which his or her personality is taken into account even before their symptom or complaint. For patients who have been treated only in a conventional manner, this initial experience contrasts starkly with their previous medical experience.

The number and type of questions patients are asked, as well as the length of time afforded them during the consultation contributes greatly to the users' impression that all aspects of their lives are taken into account and that the smallest details are important in determining the remedy.

"Certains problèmes sont nouveaux, d'autres reviennent parfois... Mon médecin regarde quand j'ai évoqué un symptôme pour la première fois, pour essayer de voir ce qui a pu se produire dans ma vie à cette époque là... Je sais que le moindre petit détail compte..." (User 5)

"De eerste keer zit ge daar zeker een uur binnen, omdat hij dus echt het kind geschetst wil zien. Waarschijnlijk als ge voor uw eigen gaat, dan zal dat ook zo zijn. Hoe voelt ze zich, hoe reageert ze op bepaalde dingen, hoe slaapt ze, de totaliteit eigenlijk dat hij probeert te weten te komen. Dan vraagt hij wat de klachten zijn en naargelang daarvan... hij zit daar ook met een hele dikke boek, waar alle middelen in staan. En ze delen de mensen in in bepaalde types, heb ik al ondervonden, hij kon dus, zonder dat hij haar goed kende, hij kon dus perfect zeggen "ijsjes vind ze leuk" en dat klopte allemaal." (User 6)

The questions asked during case-taking depend on the practitioner's approach.

"Mon homéopathe est très axé sur la transmission générationnelle, onanalyse à chaque fois mon arbre généalogique pour voir si certains phénomènes apparaissent déjà chez mes parents ou mes grands-parents" (User 5)

The emphasis placed on the **transgenerational dimension** of patient health, as well as reference to the terrain concept, establishes a link between patients and their parents and grandparents, reordering their ties of kinship and endowing them with an interpretation that may be positive or negative (where a genetically-transmitted malfunction is suspected, for example).

"Als ik kom met een klacht, dan komt dat dikwijls uit dat het normaal is dat ze dat vindt want het komt uit de vorige generaties. (User 7)

"Ik kwam bij de homeopaat en hij heeft mij vanalles gevraagd en hij heeft mij gezegd "hetgeen dat gij hebt, dat komt van iemand in uw voorgeslacht die tuberculose had". En hij heeft mij toen een pilletje gegeven en dat heet tuberculine. En ik neem dus die tuberculine al 30 jaar en dat is eigenlijk voor alles goed. Omdat dat specifiek voor mijn afweersysteem is." (user 9)

The practitioner's **empathetic attitude** and **the length of the consultation** are two of the elements most valued by users.

"J'apprécie particulièrement le temps d'écoute. Même s'il me paraît toujours trop court, il est au moins six fois plus long que chez un généraliste traditionnel..." (User 5)

"Ik vind dat een homeopaat veel beter luistert naar wat ge vertelt. Ge zit daar ook veel langer binnen." (User 8)

Patients also consider the practitioner's **listening to their concerns** as an important aspect of the homeopathic consultation, although it cannot be reduced to a form of psychotherapeutic listening. One user's comment illustrates the distinction users make between listening by a homeopath and a psychotherapist:

"Ma psy m'aidait à savoir comment faire face à certains problèmes, certaines choses parfois identifiée par mon homéopathe comme étant la source de mes symptômes... Je parlais parfois des mêmes choses aux deux, mais rarement de mes symptômes à ma psy..." (User 5)

However, we note that users do not see homeopathic consultations as a chance to talk about themselves in a narcissistic and egocentric manner. Homeopathic consultations continue to be dominated by the case-taking questionnaire.

"Je n'ai pas l'impression d'avoir un espace de parole particulier pour moi" (User 1)

#### Etiological causality

According to homeopathy users, the symptom is never reduced to a biological cause but attributed to a variety of physiological, neurological and psychological factors, or factors external to the individual which, when combined, cause an 'imbalance' in the body. The causality model vehiculated by homeopathy makes users more alert to their body's signals.

"On peut dire que grâce à l'homéopathie, je suis plus docile avec mon corps..." (User 5)

- The initial homeopathic consultation gives users the impression of being listened to and cared for 'holistically'.
- The organisation of case-taking conveys the idea of a multiple and complex etiological causality.

# 3) The social construct of the efficacy of homeopathy

The issue of the efficacy of homeopathic treatments is also indicative of the ongoing relationship between homeopathy and biomedicine. We saw earlier that user's motivations for using homeopathy were often linked with the limits of biomedicine and that homeopathy could therefore be seen as its 'missing part'. To an extent, the same applies to the efficacy of homeopathy, which many users see as effective, appropriate and sufficient for most situations, with the added advantage of being non-toxic.

"Prendre des traitements homéopathiques est en tous les cas moins agressif pour mon corps que des antibiotiques ou d'autres trucs du genre qui, pour la plupart, soignent un truc en bousillant le reste. Il suffit de lire les notices sur les effets secondaires, ça fait peur... Je n'ai jamais développé la moindre accoutumance à un traitement (homéopathique) que mon médecin m'a prescrit. De cette manière, je ne détruis pas mon foie, mes reins et tout le reste... Je suis choquée quand quelqu'un dit que ça ne marche pas. Même si je conçois que cela ne marche pas toujours, il y a des résultats, comme avec les granules d'arnica, qui ne peuvent être niés" (User 5)

« Het is niet dat we het een of het andere doen. We nemen gewoon het beste van de twee. » (user 7)

Users' reasoning tends to constantly upgrade the value of homeopathic treatments and devalue biomedicine, which they deem inadequate and reductive and accuse of being aggressive, iatrogenic and addictive. The valuation of homeopathy leads to its relative idealisation, to a large degree shielding it from the sort of criticism that users level at biomedicine.

"Nee, ik geloof ook niet in homeopathie. Ik zie dat het gaat. Dat heeft niks met geloof te maken hé." (User 9)

The safety of homeopathic treatments is therefore a key motivation for users, especially young parents wishing to safeguard their child from the iatrogenic effects of allopathic drugs.

"En même temps, une prise de granulés, ça ne peut pas aggraver la situation. A la rigueur, ce n'est pas efficace, mais cela ne peut pas aggraver le mal, tandis qu'un mauvais médicament, ça peut enclencher autre chose... Je sais que je ne peux pas faire de bêtises..." (User 4)

"Si ça ne fait pas de bien, au moins, ça ne peut pas faire de tort..." (User 3)

Dat kan gebeuren dat de ziekte verergert, maar dat is teken dat je juist zit. Maar niet dat ge u doodziek gaat voelen, maar wel harder snuiten, maar dat is maar een paar uur en dan begint dat te werken. Van dat verergeren heb ik meestal niet veel last van. (User 8)

Users also acknowledge that homeopathy is not *always* effective and that there are cases or individuals where it "doesn't work". However, they do consider it to be effective in a wide range of situations.

So homeopathy proves to be a complex and coherent therapeutic system whose efficacy is socially constructed, noted and validated:

"Pour moi, ce n'est pas que psychologique. Pour les enfants, il n'y a pas de travail sur la psychologie... Moi, quand j'ai une gastro, j'ai un remède, nux vomica, si je le prends, les vomissements s'arrêtent... Il y a une efficacité, sinon je serais allée voir un autre médecin traditionnel..." (User 4)

Given the many components of homeopathy, it would be reductive to consider only the clinical efficacy of homeopathic preparations. As a therapeutic system, homeopathy also enshrines a system of representations providing an original concept of health, illness and its management.

#### Attitudes towards health, illness and cure

The idea of health as a balance resonates with users, who find this a satisfactory representation.

"Je me suis dit que (ma fausse couche) c'était quand même un bouleversement important dans mon corps, et que ce n'était peut-être pas plus mal de m'adresser à quelqu'un qui aurait une vision un peu plus globale, visant un bien-être, un rééquilibrage, par rapport à ce que je vivais à ce moment-là, par rapport à ce traumatisme..." (User I)

- Homeopathy is considered effective in areas where allopathy is not, as though the efficacy of homeopathy is derived from the inefficacy of allopathy.
- For most ordinary ailments, homeopathy is deemed to be just as effective as allopathy, and, if not, at least it is harmless.
- An ideological valuation of homeopathy characterises users' thinking concerning the respective competencies and role of homeopathy and conventional medicine in the health system.
- However, users acknowledge that homeopathy is not always effective and does not always work on everyone.
- The efficacy of homeopathy is the subject of a social construct, built from the individual experiences of users.
- In the homeopathic system, 'health' is expressed using the concept of 'balance', which can point to different causes of 'imbalance'.

### 3.3.5.5 Users' knowledge of how homeopathy operates

In some cases, users' espousal of homeopathy seems to boil down to a relationship of loyalty to a homeopath rather than to an informed understanding of homeopathy itself. Indeed, what users know about homeopathy is only what they learn from the practitioners they consult but, while some people show little interest in the theory or philosophy of homeopathy, others have begun to learn about it.

"Je ne souhaite pas lire ou me documenter à ce sujet... J'ai une relation de confiance qui me convient très bien et ça s'arrête là. Je n'aurais d'ailleurs pas envie de lire des études qui la remettent en question..." (User 5)

Furthermore, knowledge of homeopathy by the most informed users is limited to knowledge of the remedies prescribed to them and of their indications.

"J'ai déjà pris sepia, arsenicum, mais il y a aussi kali bichromicum, coccus cacti, arnica, sépia, arsenicum album... On tourne toujours autour des mêmes, donc je sais que pour les petites diarrhées, les petites gastro, c'est tel remède..." (User 4)

Another source of this very 'pragmatic' knowledge is the small leaflets distributed free of charge in pharmacies describing the indications of some of the main homeopathic remedies, which also encourage self-medication.

"J'ai un petit ouvrage qui se donnait dans les pharmacies il y a quelques années, et qui est un peu mon livre de chevet, mais c'est juste un repère pour moi" (User 4)

## Informed self-medication in homeopathy

In a sense, the organisation of homeopathic practice helps to empower users with regard to their health, but not indiscriminately. For example, if a symptom occurs for which a user has already consulted the practitioner and been prescribed a remedy, users will tend to go and buy the same remedy without consulting their homeopath, unless it is by telephone for advice or confirmation. This telephone consultation may be subject to a (reduced) fee.

"Ce qui est chouette avec notre homéopathe, c'est qu'il fait des consultations par téléphone si c'est pour quelque chose que mes enfants ont déjà eu. A partir du moment où le médecin connaît la famille..." (User I)

"Soms bellen we ook, en dan legt ze iets klaar om te laten afhalen en dan betalen we 10 euro of soms niks." (User 2)

- Users' loyalty to homeopathy should be understood more as loyalty to a therapist.
- The distribution of small pamphlets briefly describing some homeopathic remedies contributes to 'pragmatic' self-medication by users.

# 4 THE PRACTICE

# 4.1 OBJECTIVE

Assess the practice of homeopathy in Belgium amongst practitioners affiliated to a professional organisation in Belgium.

## 4.2 METHODS

A web based survey was conducted amongst the members of the 2 professional organisations recognised in the framework of the law Colla. The questionnaire was based on experiences from previous surveys amongst osteopaths and chiropractic practitioners and acupuncturists, examples from the literature and the results of our systematic review of the effectiveness of homeopathy. The questionnaire was submitted and discussed with representatives of the 2 professional organisations in a stakeholders meeting and adaptations were made following their remarks. A question on the attitude towards vaccination was refused by the organisations and had unfortunately to be removed. Persons who did not have on line access were contacted with a paper version by mail. The web survey used Modalisa (c) software, analysis was with epi info (CDC Atlanta).

## 4.3 RESULTS

# 4.3.1 Response rate

144/330 persons answered the survey. Response rate was 39/40 for the LIGA and 115/300 for the UHB (10 persons were member of both associations).

### 4.3.2 Baseline characteristics

Sample characteristics are presented in table 1.

Table I: age, sex and professional organization of the respondents (n=144)

	All		UH	В	LIGA		
	Frequency	Percent	Frequency	Percent	Frequency	Percent	
Age (n=144)							
<30	1	0,7%	I	0,9%	I	2,6%	
31-39	8	5,6%	5	4,3%	3	7,7%	
40-49	39	27,1%	31	27,0%	8	20,5%	
50-59	59	41,0%	45	39,1%	20	51,3%	
>60	36	25,0%	32	27,8%	7	17,9%	
Sex (n=144)							
Male	85	59,0%	75	65,2%	15	38,5%	
Female	58	40,3%	39	33,9%	24	61,5%	
Professional organisation (n=	=144)						
Unio Homeopathica Belgica	105	72,9%					
Liga Homeopathica Classica	29	20,1%					
Both	10	6,9%					

# 4.3.3 Training

Table 2 shows the country where the training took place and if training was fulltime or partime. A majority got their training in Belgium.

Out of 144 respondents all but one follow one or another form of continuous education.

Table 2: Country and school where the training took place and if training was fulltime or part time (n=144)

	Al	I	UH	В	LIG	Α
	Frequency	Percent	Frequency	Percent	Frequency	Percent
Country of training (n=144).						
Belgium	137	95,1%	113	98,3%	34	87,2%
Other countries europe	38	26,4%	26	22,6%	16	41,0%
Asia	7	4,9%	4	3,5%	3	7,7%
North America	5	3,5%	5	4,3%		
South America	3	2,1%	3	2,6%		
Fulltime or partime (n=144)						
Fulltime	46	31,9%	36	31,3%	12	30,8%
Partime	94	65,3%	77	67,0%	25	64,1%
School in Belgium (n=144)						
Centre Bruxellois d'Homéopathie Uniciste	18	12,5%	18	15,7%	1	2,6%
Centre Européen d'Etude de l'Homéopathie	19	13,2%	19	16,5%	1	2,6%
Centre Liégeois d'Homéopathie	15	10,4%	15	13,0%	1	2,6%
Ecole Mosane d'Homéopathie	7	4,9%	7	6,1%		2,6%
Europees Studiecentrum Homeopathie	1	0,7%	1	0,9%	1	
Institut Médical d'Homéopathie et de Biothérapie	4	2,8%	4	3,5%	2	5,1%
Internationale School Klassieke Homeopathie	13	9,0%	11	9,6%	3	7,7%
Société Royale Belge d'Homéopathie	18	12,5%	18	15,7%	3	7,7%
Vlaamse Studievereniging voor Unitaire homeopathische	28	19,4%	27	23,5%	4	10,3%
Wetenschappelijke Vereniging voor Therapie Studie	11	7,6%	9	7,8%	3	7,7%
Centrum voor Klassieke Homeopathie	24	16,7%	7	6,1%	18	46,2%
Other	31	21,5%	27	23,5%	7	17,9%

Initial training of the respondent (table 3) are mainly medical or paramedical with a majority of general practitioners. Other initial trainings mentioned were: dietician, teacher, modern languages, eastern languages, bio-engineer, beauty-specialist, lab technician, economist.

Table 3: Initial training of the respondents (n=144)

	Al	l	UH	В	LIG	Α
	Frequency	Percent	Frequency	Percent	Frequency	Percent
No answer	10		4		6	
physician (general practicioner)	96	9,0%	94	81,7%	9	23,1%
physician (specialist)	13	66,7%	13	11,3%	3	7,7%
Physiotherapist	1	0,7%	1	0,9%		
Nurse	5	3,5%	1	0,9%	4	10,3%
Midwife	1	0,7%			1	2,6%
Veterinary	1	0,7%	1	0,9%		
Dentist	3	2,1%	3	2,6%		
Psychologist	3	2,1%			3	7,7%
Acupuncture	7	4,9%	6	5,2%	1	2,6%
Others	18	12,5%	3	2,6%	16	41,0%

Table 4 gives the way practitioners came in contact with homeopathy.

Table 4: Ways practitioners came in contact with homeopathy (n=144)

	A	II	UH	IB	LIGA		
	Frequency	Percent	Frequency	Percent	Frequency	Percent	
No answer	1		1				
Treatment that practicioner underwent himself	54	37,5%	37	32,2%	20	51,3%	
Treatment of a relative or friend	44	30,6%	37	32,2%	10	25,6%	
Conference	13	9,0%	13	11,3%	4	10,3%	
Written sources	34	23,6%	28	24,3%	11	28,2%	
Internet	2	1,4%	1	0,9%	1	2,6%	
Others	33	22,9%	30	26,1%	5	12,8%	

# 4.3.4 Practice.

The mean time in practice was 17 years (Standard deviation 10),median 18 interquartile range 7 to 26, min 3 year and max 36, Table 5 shows the practices that are combined with homeopathy.

Table 5: Other professions (n=144)

type of practice :	Frequency	Percent
General practice Acupuncture Nursing Physiotherapy Oriental medicine Osteopath/chiropractic Dentistry	103 35 0 0 10 3	71,5% 24,3% 0,0% 0,0% 6,9% 2,1% 2,1%
Veterinary other	1 23	0,7% 16,0%

The median % of the time that a practitioner spends on homeopathy is 80% (no means are given as distribution was too skewed), interquartile range 40% to 90%, min 0% and max 100%. Members from the LIGA had a somewhat lower median (55) but difference was not statistically significant.

Table 8 gives the fees asked for different types of consultations, members of LIGA are on average somewhat more expensive.

Table 8: Fees for different types of consultations (n=144)

	Al	I	UHI	3	LIG	A
	Frequency	%	Frequency	%	Frequency	%
Initial fee ADULT						
Non réponse	8	5,6%	7	6,1%	2	5,1%
<35euros	18	12,5%	17	14,8%	1	2,6%
35-50euros	41	28,5%	35	30,4%	8	20,5%
50-80euros	70	48,6%	50	43,5%	25	64,1%
>80euros	7	4,9%	6	5,2%	3	7,7%
Initial fee CHILD						
Non réponse	7	4,9%	6	5,2%	1	2,6%
<35euros	23	16,0%	22	19,1%	1	2,6%
35-50euros	59	41,0%	47	40,9%	15	38,5%
50-80euros	55	38,2%	40	34,8%	22	56,4%
Follow up fee ADULT						
Non réponse	9	6,3%	8	7,0%	2	5,1%
<35euros	52	36,1%	43	37,4%	11	28,2%
35-50euros	77	53,5%	58	50,4%	23	59,0%
>50euros	6	4,2%	6	5,2%	3	7,7%
Follow up fee CHILD						
Non réponse	10	6,9%	9	7,8%	1	2,6%
<35euros	62	43,1%	51	44,3%	14	35,9%
35-50euros	65	45,1%	48	41,7%	21	53,8%
>50euros	7	4,9%	7	6,1%	3	7,7%

Table 6 shows the place of practice and practice area. The large majority practices at home followed by a cabinet outside the house. Results for both professional associations are very similar (data not shown).

Table 6. Place of practice and practice area (n = 144)(more than one answer possible).

place of practice	Frequency	Percent
At home	104	72,2%
In a cabinet outside the house	48	33,3%
hospital	1	0,7%
policlinic outpatient department	1	0,7%
patients house	23	16,0%
Type of practice		
Solo	113	78,5%
Group practice	35	24,3%
Province		
Antwerpen	29	20,3%
Oost Vlaanderen	12	8,4%
West Vlaanderen	14	9,8%
Limburg	11	7,6%
Vlaams Brabant	14	9,8%
Bruxelles/Brussel	27	18,9%
Brabant Wallon	10	8,3%
Luxembourg	2	1,4%
Namur	7	4,9%
Hainaut	5	3,5%
Liège	6	4,2%
More than one	6	4,2%

# 4.3.5 Workload and profile of patients.

Table 9 shows the number of patients seen in a day, duration of a consultation and the proportion of patients coming for a new indication. The majority sees between 5 and 10 patients a day and the majority of the consultations last between  $\frac{1}{2}$  and  $\frac{1}{2}$  hour a day. There are some differences between members from LIGA and UHP, members of the LIGA have a higher proportion of consultation of more than an hour.

Table 9. Number of patients seen in a day, duration of a consultation and the proportion of patients coming for a new indication (n = 144).

number of patients a day								
	Frequency	%						
<5	52	36,1%						
6 to 10	56	38,9%						
>10	32	22,2%						
Duration of a consultation	New consultat	tion (n = 144)	Follow up consultation (n = 144)					
Adults	Frequency	%	Frequency	%				
<30min	5	3,5%	30	20,8%				
30min-1h/u	40	27,8%	90	62,5%				
1h/u-1h/u30	59	41,0%	16	11,1%				
1h/u30-2h/u	25	17,4%	3	2,1%				
>2h/u	8	5,6%	1	0,7%				
Duration of a consultation	New consulta	tion (n =144)	Follow up consultation (n = 144					
Child	_	0/	Frequency	0/				
Child	Frequency	%	rrequency	%				
<30min	Frequency 10	<b>%</b> 6,9%	52	<b>36,1%</b>				
			• •					
<30min	10	6,9%	52	36,1%				
<30min 30min-1h/u	10 74	6,9% 51,4%	52 76	36,1% 52,8%				
<30min 30min-1h/u 1h/u-1h/u30	10 74 33	6,9% 51,4% 22,9%	52 76 10	36,1% 52,8% 6,9%				
<30min 30min-1h/u 1h/u-1h/u30 1h/u30-2h/u	10 74 33 20	6,9% 51,4% 22,9% 13,9%	52 76 10	36,1% 52,8% 6,9%				
<30min 30min-1h/u 1h/u-1h/u30 1h/u30-2h/u >2h/u	10 74 33 20	6,9% 51,4% 22,9% 13,9%	52 76 10	36,1% 52,8% 6,9%				
<30min 30min-1h/u 1h/u-1h/u30 1h/u30-2h/u >2h/u Gender of patients (n = 144)	10 74 33 20 3	6,9% 51,4% 22,9% 13,9% 2,1%	52 76 10	36,1% 52,8% 6,9%				
<30min 30min-1h/u 1h/u-1h/u30 1h/u30-2h/u >2h/u Gender of patients (n = 144) Mainly male	10 74 33 20 3	6,9% 51,4% 22,9% 13,9% 2,1%	52 76 10	36,1% 52,8% 6,9%				
<30min 30min-1h/u 1h/u-1h/u30 1h/u30-2h/u >2h/u Gender of patients (n = 144) Mainly male Mainly female	10 74 33 20 3 1 67 71	6,9% 51,4% 22,9% 13,9% 2,1% 0,7% 46,5% 49,3%	52 76 10 2	36,1% 52,8% 6,9% 1,4%				

	First year		Second year	
	Frequency	%	Frequency %	
< 1			16	11,1%
1 to 3	33	22,9%	95	66,0%
4 to 6	75	52,1%	24	16,7%
7 to 9	23	16,0%	1	0,7%
10 to 12	5	3,5%	1	0,7%
> 12	1	0,7%		

# 4.3.6 Age

Figure I shows the distribution of the age groups practitioners state that they see and are specialized in.

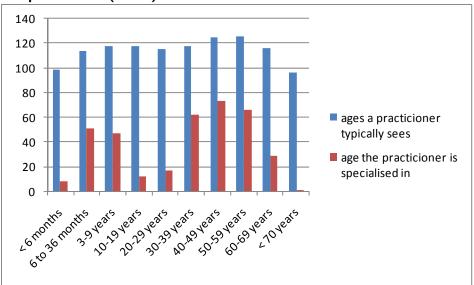


Figure 1: distribution of the age groups practitioners state that they see and are specialized in (n=144).

#### 4.3.7 Provider delay

For a new patient, the median delay is 7 days (no means are given as distribution was too skewed to the left), interquartile range 1,5 to 15, min 0 and 365, other patients can in nearly all cases be seen the same day.

Practitioners from the UHP see a median of 120 patients a month (interquartile range 60 to 200) and a median of 10 new patients a month (interquartile range 7 to 12) Practitioners from the LIGA see a median of 15 patients a month (interquartile range 6 to 30) and a median of 3 new patients a month (interquartile range I to 7) Practitioners member from both see a median of 80 patients a month (interquartile range 50 to 150) and a median of 12.5 new patients a month (interquartile range 10 to 40). No means are given as distributions were skewed.

Figure 2 shows the proportion of patients consulting for preventive reasons, the majority of practitioners has around 10 % of their patients coming for prevention.

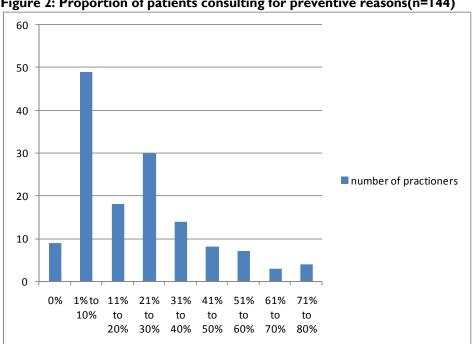


Figure 2: Proportion of patients consulting for preventive reasons(n=144)

## 4.3.8 Patient referral:

Practitioners were asked to rank from I to 8 where most referrals came from. Most were referred by a relative/friend. There are few differences by professional organisation. Table I0a gives the rankings for each type of referral, table I0b gives the average ranking per type of referral and for the two professional groups (so the lower the number the higher the average rank).

Table 10a: Source from where the patient was referred, practitioners were asked to rank from 1 to 6. (N = 144)

Ranking	1	%	2	%	3	%	4	%	5	%	6	%	7	%	8	%	total
Referred by physician	5	3,6	13	10	22	18,3	25	23,3	17	18,4	12	15,5	9	14	15	25,4	118
Referred by another conventional health care prov	2	1,4	21	16,1	24	20	16	14,9	18	19,5	15	19,4	9	14	2	3,3	107
Referred by another non- conventional health care	3	2,1	33	25,3	19	15,8	19	17,7	9	9,7	8	10,3	7	10,9	2	3,3	100
Referred by a friend or relation	100	72,4	16	12,3	4	3,3	1	0,9	6	6,5	1	1,2	0		1	1,6	129
Website	5	3,6	23	17,6	15	12,5	12	11,2	13	14,1	10	12,9	10	15,6	9	15,2	97
Not referred	12	8,6	14	10,7	18	15	18	16,8	9	9,7	13	16,8	5	7,8	0		89
Doesn't know	4	2,8	4	3	11	9,1	8	7,4	14	15,2	10	12,9	14	21,8	10	16,9	75
Others	7	5	6	4,6	7	5,8	8	7,4	6	6,5	8	10,3	10	15,6	20	33,8	72

Table 10b: Average ranking by professional organisation(n=144)

	average rank			
Ranking	All	UHB	LIGA	
Referred by physician	4,55	4,47	4,71	
Referred by another conventional health care provider	4,1	4,08	4,03	
Referred by another non- conventional health care provider	3,6	3,46	3,76	
Referred by a friend or relation	1,48	1,4	1,75	
Website	4,23	4,25	4,4	
Not referred	3,64	3,88	3,18	
Doesn't know	5,13	5,22	5,1	
Others	5,27	5,41	5,45	

# 4.3.9 Claims for which homeopathy is used.

Table II gives the frequency of the complaints for which patients come consulting, ranked by importance (where often and very often was mentioned most). Upper respiratory tract infection (URTI), depression and anxiety, insomnia and acute otitis, are the most frequently mentioned conditions. We did not see differences between professional organisations.

Table II: Frequency of the complaint for which patients come consulting, ranked by importance (n=144) (where often and very often was mentioned most)

	Often or very often		Sometimes or rarely		never		No answer	
Condition	n	%	n	%	n	%	n	
URTI	111	83%	20	15%	<u>n</u> 3	2%	10	
Depression and anxiety	111	80%	26	19%	2	1%	5	
Insomnia	101	74%	35	26%	1	1%	7	
Acute otitis	94	68%	35	25%	9	7%	6	
Low back pain	90	67%	40	30%	4	3%	10	
Chronic fatigue	89	64%	43	31%	6	4%	6	
LRTI	85	63%	46	34%	4	3%	9	
Diarrhea	84	63%	49	37%	1	1%	10	
Asthma	79	58%	54	39%	4	3%	7	
Warts	73	56%	53	41%	4	3%	, 11	
Allergy	76	54%	61	44%	3	2%	4	
Premenstrual syndrome	67	49%	65	47%	5	4%	7	
Skin disease	61	46%	56	42%	15	11%	10	
Pregnancy	57	42%	65	48%	13	10%	9	
Fibromyalgia	56	41%	71	52%	9	7%	8	
Cancer side effects	51	38%	66	49%	18	13%	9	
Conjunctivitis	48	36%	78	58%	9	7%	9	
ADHD	48	35%	84	61%	5	4%	7	
Venous insufficiency	35	27%	87	66%	10	8%	10	
Enuresis	30	22%	94	69%	12	9%	8	
Obesity	24	18%	98	73%	12	9%	10	
HIV	5	4%	45	35%	80	62%	14	
Dementia	2	1%	91	68%	41	31%	10	

### 4.3.10 Type of medicines used and type of homeopathy practiced.

Medicines with korsakovian method of manufacture (multi-flask method here denoted as K) are more often prescribed (91,7%) than medicines with hahnemanian method of manufacture (single-flask method, here denoted as CH) (69,4%).

Low or middle dilutions are more often prescribed than high or very high dilutions.

Table 12: Dilutions used (expressed as CH) (n=144)

	%
Low dilutions (<12CH )	63,0%
High or very high dilutions (>12CH)	37,0%

Therapists use a variety of homeopathic approaches: 'classicist—unicist' homeopaths are loyal to Hahnemann's teachings and seek a single remedy tailored to each individual patient. They represent the great majority of homeopaths affiliated with a professional association (see next table). 'Complex—pluralist' homeopaths prescribe a combination of 'contextual' and 'fundamental' remedies. Finally, clinical homeopaths favour the use of homeopathic remedies designed to act on a specific organ or system. These remedies may or may not be delivered in complex form and usually in low dilution.

Table 13: Type of homeopathy practices (n=144)

	All		UHB		LIGA	
	Frequency	%	Frequency	%	Frequency	%
No answer	3		2		1	
Classic/unicist	108	75,0%	80	69,6%	36	92,3%
Complex	19	13,2%	19	16,5%	1	2,6%
Clinical	29	20,1%	28	24,3%	1	2,6%
Others	5	3,5%	4	3,5%	2	5,1%

### 4.4 DISCUSSION

This survey gives a description of the profile of homeopaths that are affiliated to a professional organisation, as stated in the objective. We have no information about non affiliated practitioners, which is a major limitation as affiliated members probably only represent 10 % of the practitioners, their profile may be different as those professional organisations have a number of requirements concerning training and practice and there may be considerable differences in attitude, degree and way homeopathy is used amongst them. Another major limitation was the fact that the professional organisations censored our questionnaire and refused questions about use and attitude towards vaccination, we know from our in depth interviews that there is resistance towards vaccination among practitioners, but due to this refusal we do not have more information on this problem. Surveys in Germany, Austria, Australia and the USA documented resistance against vaccination in similar surveys<sup>73, 74</sup>. This also implies that the survey should be rather seen as a description of what the professional organisations choose to reveal about their profile. Response rate was good compared with other similar surveys, but was lower for the UHP. According to stakeholders from the UHP this would still be a consequence or resistance towards the remaining questions. We could find very few differences between practitioners from both professional organisations.

# 5 ORGANISATIONAL AND LEGAL ASPECTS

## 5.1 BELGIAN AND EUROPEAN LEGAL FRAMEWORK

This chapter is common to the three reports on alternative medicines, as most of the issues are common to all non-conventional practices (except the part on homeopathic remedies).

#### 5.1.1 Introduction

This chapter provides details of the Belgian and European legal framework in which non-conventional practices may or may not be exercised.

Points 5.1.3 to 5.1.6 describe the Belgian legal context for both conventional and non-conventional practices. In addition to Royal Decree n° 78 (points 5.1.3.1 to 5.1.3.6), the 'Colla' law is also examined, paying special attention to the *ratio legis* (point 5.1.4.1) and the current situation (point 5.1.3.2). In point 5.1.5, the chapter analyses the interactions between Royal Decree n° 78 and the Colla law, as well as the consequences of exercising (non-)conventional healthcare (point 5.1.6). Finally, point 5.1.7 reviews the practice of non-conventional medicine in the European context. It also provides a brief overview of the legal context in the Netherlands, France and Great Britain.

## 5.1.2 Methodology

In this review of legislation, doctrine and jurisprudence, the Juridat and Jura databases and the official internet sites of the Belgian courts were consulted. Doctrine and jurisprudence, as published in the main legal reviews, such as Revue de Droit de la Santé and Rechtskundig Weekblad, were also consulted. As for unpublished jurisprudence, the parties concerned were contacted in order to consult the jurisprudence in question, as well as for consent to exploit it anonymously. Finally, the main reference works by experts in this field were also consulted.

# 5.1.3 The exercise of conventional healthcare in Belgium under the terms of Royal Decree no. 78

The description of the exercise of conventional healthcare is found mainly in Royal Decree no. 78 of 10 November 1967 concerning the exercise of the healthcare professions. For reasons of convenience, this Royal Decree will be referred to as 'Royal Decree no 78'.

### 5.1.3.1 Exercise of the art of healing

Royal Decree no. 78 makes a distinction between the art of healing and medicine. In the Royal Decree, the 'art of healing' extends to the medical arts, including dentistry, exercised on humans, the pharmaceutical arts in all their aspects (preventive or experimental), curative, continuous and palliative. Doctors, dentists and pharmacists therefore practice the art of healing.

## 5.1.3.2 The practice of medicine

In the Royal Decree the practice of medicine refers to any act intended or presented as having the aim, with respect to humans, of examining the state of health, or identifying illnesses and disorders, making a diagnosis, setting up or carrying out the treatment of a pathological, physical or mental condition, real or assumed, or vaccination. In Belgium, the legislature has decided to give doctors a legal monopoly on medicine. Only persons satisfying the defined conditions, namely holders of a suitable diploma or with the approval of the Directorate General for the health professions of the federal public health service and registered in the order of doctors, can practice medicine. This monopoly is exclusive.

In other words, only doctors are authorised to practice medicine, to the exclusion of all others. There are only two exceptions to this rule: midwives and dentists, who are also authorised to practice medicine, each in their specific field.

Moreover, this monopoly of doctors is also general in a way that each doctor is authorised to carry out all medical acts, whatever their (sub-)specialisation.<sup>76</sup>

#### 5.1.3.3 The exercise of physiotherapy

The exercise of physiotherapy is also subject to legal conditions, namely holding a certificate of recognition delivered by the Minister for Public Health and having a diploma approved by the Directorate General for the health professions of the federal public health service. The exercise of physiotherapy is not reserved exclusively for physiotherapists; it is also open to doctors (even with no specific recognition). Conversely, physiotherapists are not allowed to practice medicine. In addition, physiotherapists are not allowed to practice physiotherapy without a prescription from a doctor, failing which they could be found guilty of the illegal practice of medicine, provided that such practice took place on a regular basis.<sup>76</sup> The interpretation of a 'regular' basis is left to the discretion of the trial judge. Certain judges have already deemed that only two or three acts can be considered as 'regularly' (e.g. Cass., 20 September 1937, Ghent, 2 February 1965). It has also been judged that a regular basis should not be considered from a mathematical standpoint, but depends on the circumstances and specifics of each case. Acts are considered to be exercised on a regular basis when they are neither exceptional nor accidental (Corr. Namur, 13 October 1982).76

## 5.1.3.4 Exercise of the art of nursing

The exercise of the art of nursing is also subject to several legal conditions, namely having the required certificate, having this certificate recognised and having obtained the approval of the Directorate General for the health professions of the federal public health service. In addition, the law has subdivided the acts that can only be carried out by nursing staff into acts A, BI, B2 and C.<sup>76</sup>

## 5.1.3.5 The exercise of the paramedical professions

The exercise of paramedical professions is also governed by the law. Several Royal Decrees have described precisely the exercise of these professions, the professional certificates required, the mandatory qualifications, the list of acts and practices that can be carried out by the practitioners of these professions and their modalities. Under the law, the term 'paramedical professions' covers the following professions:

medical laboratory technician, logopaedist, occupational therapist, truss maker, orthotist, prosthetist, dietician, medical imagery technician, assistant pharmaceutical technician, orthopaedist and chiropodist. The practitioners of a paramedical profession must have a professional certificate approved by the Directorate General for the health professions of the federal public health service. When granting its approval, the commission registers the practitioner.<sup>76</sup>

### 5.1.3.6 Exercise of the profession of midwife

In an exception to the monopoly on the exclusive practice of medicine granted to doctors, holders of a midwifery diploma are authorised to carry out the medical act of normal childbirth<sup>76</sup>, provided that their certificate has been approved in advance by the competent medical commission. In addition, the law enumerates the activities that midwives can carry out alone, as well as the acts that they cannot perform.

# Key messages: The exercise of conventional healthcare in Belgium under the terms of Royal Decree no. 78

- In Royal Decree no. 78, the 'exercise of conventional healthcare' refers to the exercise of the art of healing, medicine, physiotherapy, nursing, the paramedical professions and midwifery.
- Each of these forms of exercise of conventional healthcare is subject to specific conditions.

# 5.1.4 The exercise of non-conventional medicine in Belgium

#### 5.1.4.1 The Colla law

#### The structure of the law

A big step towards recognition of the exercise of (certain forms of) non-conventional medicine was taken with the law of 29 April 1999 concerning non-conventional practices in the field of medicine, pharmaceuticals, physiotherapy, nursing and the paramedical professions (Official Journal of 24 June 1999). For convenience, this law will be referred to hereafter as the 'Colla law'.

The Colla law is a brief framework law with only a small number of articles: article I (reference to article 78 of the Constitution), article 2 (definitions, establishment of chambers), article 3 (joint committee), article 4 (effects of certain Royal Decrees), article 5 (joint committee), article 6 (chambers), article 7 (procedure), article 8 (individual registration), articles 9 et 10 (duty of information), article II (penal provisions) and article I2 (entry into force of certain articles).

#### The rationale for the law

In view of the fact that a large number of people throughout the world were making extensively use of the services of certain non-conventional practices and that several European Union countries had already made moves to regulate such practices, a debate concerning the registration of non-conventional practices was urging. Because there was no specific regulation in Belgium, until that time anyone could practice various forms of treatment without any guarantees concerning quality or training. It was also believed that certain non-conventional practices were sufficiently substantiated to justify setting up a legal framework. The purpose of this framework was to define rules to guarantee that patients receive quality care. The result of this process is a dual registration system for both non-conventional practices and their practitioners. The framework law defines the basic conditions for setting up the two registration systems. The registration of a non-conventional practice has the effect of placing it within the legal framework of the Colla law, providing guarantees for patients.<sup>77 no. 1714/1</sup> Individual registration guarantees to patients that the practitioner in question satisfies the general conditions applicable to the exercise of non-conventional practices and to the specific conditions applicable to individual registration. This mechanism gives patients the certainty that they are dealing with a competent practitioner. It is also important for the individual practitioners, who thereby ensure that their non-conventional practices are not branded the illegal practice of medicine, and can exercise them perfectly legally, provided that they comply with the rules in force.

#### Non-conventional practices

The Colla law defines non-conventional practices as the habitual practice of acts intended to improve and/or preserve human health, exercised according to the rules and conditions stipulated in this law. The law considers homeopathy, chiropractic, osteopathy and acupuncture to be practices that meet this definition. The law also stipulates that other practices may be considered as such in the future, provided that the King institutes chambers for this purpose.

#### The joint committee

The Colla law stipulates that a joint committee must be set up at the Ministry of Health, and that this committee will have to play a key role in the application of the law.

This joint committee is composed of several chambers. More specifically, the Colla law stipulates a chamber for each of the non-conventional practices, i.e. homeopathy, chiropractic, osteopathy and acupuncture.

Within six months after its constitution, the joint committee is required to formulate an advice on the general conditions applicable to the exercise of all non-conventional practices. This advice relates in particular to professional insurance and minimum coverage, membership of a recognised professional organisation, a registration system, an advertising system (enabling the general public to obtain information concerning registered practices and registered practitioners), and a list of acts not authorised for non-medical practitioners. The general conditions are determined by the King on the basis of this advice, by a decision deliberated in the Council of Ministers. Only when this advice has been formulated the law can be applied in practice.<sup>78</sup>

In addition to the general conditions, the committee must also formulate an advice concerning the registration of non-conventional practices and the individual registration of practitioners.

The composition of the joint committee and the conditions under which they can issue an advice are defined by the law. Until today (end of 2010), these provisions have not yet been implemented.

#### The chambers for non-conventional practices

The Colla law introduces a chamber for each of the non-conventional practices that it recognises (homeopathy, chiropractic, osteopathy and acupuncture). Moreover, the King is authorised to establish additional chambers in the future for other non-conventional practices. He can proceed with the establishment of such chambers at his own initiative or at the request of the recognised professional organisations concerned. This refers to professional organisations of practitioners of a practice that could be considered for qualification as a non-conventional practice recognised by the King on the basis of the criteria defined by Him concerning the legal personality, the list of members, the commitment to participate in scientific research and an external evaluation.

The chambers have the task of issuing an advice during the registration of a non-conventional practice, as well as during the individual registration of one of its practitioners. Each chamber also defines the directives concerning the proper exercise of the practice in question and it advises the minister on the organisation of a peer review system and professional ethical rules.

The composition of the chambers and the voting procedures are defined by the law.

# The procedure

Concerning the procedural modalities to be followed by the joint committee and the chambers, the Colla law stipulates only that it is up to the King to fix the other provisions concerning the organisation and working methods of the joint committee and the chambers, which has not been done to date.

#### The conditions of exercise for a registered non-conventional practice

As mentioned above, we must first wait for the advice of the joint committee concerning the general conditions applicable to the exercise of all non-conventional practices. Based on this advice, the King will then define the general conditions by a decision deliberated in the Council of Ministers. Only then the Colla law can be effectively applied.

In addition, registration of individual practitioners of registered non-conventional practices must be set up. Under the terms of the Colla law, no one can exercise one of the registered non-conventional practices or perform acts that form part of this practice without prior registration. Registration is granted by the minister, on the advice of the chamber concerned, provided that the applicant satisfies the general conditions and any conditions specific to the registered non-conventional practice. The Colla law defines the procedures to follow, but they have to be further executed by the King.

As for individual registration, the Colla law stipulates that it can be suspended or withdrawn, as a punishment for failure of the practitioner to comply with the provisions of the law or its executory decisions. Suspension (for a maximum period of one year) or withdrawal of individual registration is ordered by the minister at the proposal of the chamber concerned. Once again, the law defines a procedure that has yet to be implemented by the King (the law itself does not stipulate an appeal procedure).<sup>79</sup>

The Colla law also stipulates sanctions in the case of exercise of one of the non-conventional practices, or habitually dispensing treatments linked to such registered non-conventional practices, without being registered where registration has been suspended or withdrawn. These offences are punishable by a fine and/or a prison sentence.

#### Obligations of the practitioners of a registered non-conventional practice

The Colla law imposes an obligation of information on all practitioners of a registered non-conventional practice.

This obligation first stipulates keeping a *record* for each patient. No specific sanction has been defined for failure to comply with this obligation, which does not mean that it could not justify the suspension or withdrawal of individual registration.<sup>78</sup>

In accordance with the Colla law, a practitioner of a non-conventional practice may only provide a treatment for the patient after having received a recent diagnosis concerning the complaint, drawn up in writing by a doctor. This obligation only applies to practitioners who are not at the same time doctors. The patient is however allowed to refrain from a preceding doctor's consultation. In this case, the patient must confirm this decision in writing and this document must then be attached to the patient's record. Failure to respect this obligation may not only be punishable by withdrawal or suspension of individual registration, but also a sanction (in the form of a fine). Moreover, it emerges from preparatory parliamentary works that failure to respect this obligation by a non-doctor practitioner does not exonerate practitioners from their own responsibility. Non-conventional practitioners remain responsible for the indication of the treatment that they intend to undertake, without subsequently being able to evade responsibility under the sole pretext of an (erroneous) diagnosis of a doctor.<sup>80 no.</sup> 1714/3

Another obligation for practitioners of a registered non-conventional practice is the *duty of care*. Under this obligation, the practitioner must take all necessary precautions to avoid the patient being deprived of conventional treatment. It emerges from preparatory parliamentary documents that this only concerns vital treatments for the patient. The practitioner must, for example, draw the attention of the patient to the need, where appropriate, to consult a doctor. <sup>80</sup> no. 1714/3

In the context of this duty of care, the practitioner of a non-conventional practice who is not a doctor is required to *inform* a doctor, at the doctor's request, of the evolution of the health of the patient. However, this exchange of information cannot take place without the consent of the patient. The practitioner can also supply or obtain information from another practitioner of a non-conventional practice. Finally, the Colla law also stipulates that doctors can also solicit at their own initiative information concerning the evolution of the health of their patients from a non-doctor practitioner of a registered non-conventional practice, but only in the interest of the patient and with the patient's consent. It should be noticed that the Colla law only refers to the evolution of the health of the patient, and not the treatment chosen.<sup>78</sup>

The Colla law also mentions explicitly the applicability of article 458 of the criminal code (*professional secrecy*) to the non-doctor practitioners of a non-conventional practice.

The applicability of the Patients Rights Act of 22 August 2002 to practitioners of a non-conventional practice is examined in point 5.1.5.2.

# 5.1.4.2 The Colla law today

#### The choice of a framework law

During the elaboration of the Colla law, the legislature opted for a framework law. The purpose of this framework law is to offer patients various general guarantees before providing a more detailed formulation of the concrete conditions regarding training, assessment, ethics, practitioner registration, etc. Since it seemed neither possible nor desirable for the public authorities themselves to assume this task of detailed formulation, the legislature opted for a framework law, which mainly defines the procedure to follow. The key element of this framework law is the introduction of a joint committee, within which both traditional medicine and non-conventional practices are represented, which is tasked with determining which non-conventional practices are eligible for registration, and above all to define the conditions governing their exercise.<sup>81</sup> no. 1-1310/3

#### **Entry into force**

As to the date on which the Colla law enters into force, a distinction must be made between articles 3, 8, 9, 10 and 11 and the other articles. Whereas articles 3 (joint committee), 8 (individual registration), 9 (obligations), 10 (relationship with Royal Decree no. 78) and 11 (penal provisions) will only enter into force six months after the first day of the month following the entry into force of the appointment of the members of the joint committee, the other articles have already been in force since 4 July 1999.

## The implementing orders

More than ten years later, four implementing orders concerning the Colla law have been issued. They all relate to article 2, §1, 3°, namely the recognition of professional organisations.

The first implementing order is the Royal Decree of 4 July 2001 concerning the recognition of professional organisations of practitioners of a non-conventional practice or a practice that could be qualified as non-conventional (Official Journal of 19 January 2002).

This Royal Decree defines the conditions that a professional organisation must satisfy to obtain and retain recognition as a non-conventional practice. Recognition is granted by Royal Decree for a renewable period of six years. The procedure for the submission of a request for recognition is defined by the competent health minister. The minister defined these modalities in the ministerial order of 30 September 2002 defining the modalities for requesting recognition as a professional organisation of practitioners of a non-conventional practice or another practice that could be qualified as non-conventional (Belgian Official Journal of 5 December 2002).

The second implementing order is the Royal Decree of 10 February 2003 recognising professional organisations of practitioners of a non-conventional practice or a practice that could be qualified as non-conventional (Official Journal of 26 February 2003). Through this Royal Decree, ten professional organisations of practitioners of non-conventional practices or practices that could be qualified as non-conventional were recognised.

The third implementing order is the Royal Decree of 10 November 2005 recognising professional organisations of practitioners of a non-conventional practice or a practice that could be qualified as non-conventional (Official Journal of 9 December 2005). Through this Royal Decree, two new professional organisations were recognised.

The fourth and last implementing order is the Royal Decree of 6 April 2010 recognising professional organisations of practitioners of a non-conventional practice or a practice that could be qualified as non-conventional (Belgian Official Journal of 12 April 2010). Through this Royal Decree, nine professional organisations saw their recognition renewed and two new organisations of practitioners of a non-conventional practice were recognised.

#### The consequences of restricted execution

The Colla law cannot be applied at the moment because it has not been sufficiently executed.

The joint committee tasked with issuing an advice concerning the general conditions for the exercise of all non-conventional practices, their registration and conditions for individual registration not yet having been constituted, the committee has not yet started its work. One notable consequence of this situation is that the practitioners of non-conventional practices (such as osteopaths, chiropractors, acupuncturists and homeopaths) who are not doctors are not currently allowed to perform acts relating to medicine. If they do not comply with this prohibition, they become guilty of the illegal practice of medicine, which is punishable by the law. Certain professionals such as physiotherapists can however practice on medical prescription certain treatments that can be considered as alternative treatments.

Patients are also waiting for quality guarantees covering the exercise of non-conventional practices because, at the present time, practically anybody can exercise non-conventional practices without the benefit of any training.

#### The condemnation of the Belgian state

It is precisely because of this non-execution of the Colla law that the professional association *Le Registre des Ostéopathes de Belgique* summoned the Belgian state, in May 2008, before the Brussels court of first instance. On 22 January 2010, this court issued a judgement condemning the Belgian state. The court considered that the Belgian state was in default because of the non-execution of the Colla law within a reasonable period. This default results in prejudice to third parties, in particular professional associations, and compromises the honour and reputation of the professional organisation and its members. In this instance, there would have been no prejudice if the joint committee had been set up and if it had been in a position to carry out its task, in accordance with the Colla law.

Since damages in kind had been requested, the court sentenced the Belgian state to set up the joint committee as stipulated in the Colla law, in accordance with the legal provisions, on pain of being compelled to pay 5 000 euros per month of default after a period of three months following notification of the judgement. After June 2010, the state must pay a penalty of 5 000 euros a month to two associations of osteopaths.

#### A few remarks concerning the execution of the Colla law

There are a number of elements that make it difficult to implement the Colla law.

#### THE COMPOSITION OF THE JOINT COMMITTEE

The joint committee must be composed mainly of 'practitioners of a non-conventional practice' (art. 5). It is not stipulated in article 5 whether these members must be registered individually. Neither does the law provide a definition of a 'practitioner of a non-conventional practice'. As a result, it is not clear whether the law requires these practitioners to be registered for the composition of the first joint committee.

The law states that nobody can exercise a non-conventional practice without being registered (Art. 8 §1). In addition, the professional exercise of a non-conventional practice by a non-doctor is equivalent to the illegal practice of medicine, which is punishable (although recent jurisprudence tends to temper this position and certain non-conventional practices can be found in the practices legally authorised for physiotherapists on medical prescription)<sup>75</sup>. If we keep to this interpretation that individual registration is not required to assemble the joint committee for the first time, it is possible that certain members of this committee would be guilty of the illegal practice of medicine. In order to comply with current legislation (the Colla law and Royal Decree no. 78) the joint committee could only be composed of doctors. This would go completely against the 'joint' character specified in the law. In addition, there remains the problem that doctors who also resort to non-conventional practices and sit on the joint committee as 'practitioners of a non-conventional practice', must also as doctors satisfy the conditions of the Colla law and therefore be registered individually.

If we consider that individual registration is necessary for constitution of the first joint committee, the problem arises that individual registration is only possible if the registration conditions are established by Royal Decree. This Royal Decree containing the registration conditions is solely possible following an advice of the joint committee. But the joint committee cannot be constituted as long as there are no (registered) practitioners of a non-conventional practice. Based on this interpretation, the law would have to be changed in order to break out of this vicious circle<sup>82, 83</sup>. The composition of the joint committee without first amending the law involves a potential risk of a legal challenge to the composition of the joint committee (including all decisions taken by the joint committee that have legal consequences).

CONFIRMATION BY THE LAW OF THE ROYAL DECREE OF 6 APRIL RECOGNISING THE PROFESSIONAL ORGANISATIONS OF NON-CONVENTIONAL PRACTICES OR PRACTICES THAT COULD BE CONSIDERED FOR QUALIFICATION AS A NON-CONVENTIONAL PRACTICE

It would seem right and proper that a framework law should always be accompanied by long-term work on its implementation. The entry into force of the law always depends on the promulgation of numerous decrees. Moreover, several implementing orders must subsequently be approved by the parliament.

The Royal Decree of 6 April 2010 illustrates this, taking into account the recognition of professional associations for a non-conventional practice or a practice that could be considered for qualification as a non-conventional practice<sup>84</sup>. Recognition of professional unions is necessary for the constitution of the joint committee. The law confirmed this Royal Decree on 19 November 2010.

According to the Colla law, the Royal Decree cannot enter into force unless it is ratified by the law within six months of its publication in the Belgian Official Journal.

In this particular case, the Royal Decree of 6 April 2010 was published in the Belgian Official Journal of 12 April 2010. This means that, in order to be applicable, it would have to be ratified by the Chamber and the Senate at the latest on 12 October 2010. Since ratification took place on 19 November 2010, it came too late.

It could be argued that the legislator cannot in principle commit its successors. Consequently, a new legislator must be able to decide to ratify this law after this period of six months. However, this reasoning raises the question of whether such a process complies with the principle of equality (articles 10 and 11 of the Constitution), a general principle that states that each citizen has (legally) the same rights and must be treated in the same way in the same situation. One might wonder whether the fact of changing the general rule with an individual legal application would prejudice the fact that each citizen, in the eyes of the state, has the right to the same application of the law. Indeed, by ratifying individual recognition of the professional associations after the period of six months, the legislator has departed from the general rule. The members of the professional association that will be recognised in the future therefore have no legal guarantee as to the delays in which their 'Royal Decree of recognition' would be confirmed by the law.

The consequence of late ratification is that the Royal Decree concerned cannot be executed and the legal effects cannot take place (such as the establishment of chambers).

One possible solution would be to publish the Royal Decree again and have it properly ratified within six months.

#### INTEGRATING LEGISLATION AND PRACTICE

Execution of the Colla law is also complicated by the fact that non-conventional practices have developed since 1999 and have enjoyed uninterrupted growth, which does not seem to be affected by the lack of development of the legal framework. Acupuncture is now taught in several faculties of medicine, the ULB offers a course in osteopathy, and various services are now reimbursed by the sickness funds in the context of complementary insurance. These developments should be analysed carefully before the implementation of the framework law<sup>85</sup>. Legislation and practice are both evolving at their own pace, which complicates the legislative delay.

Neither is the execution of the law made any easier by the very different contexts of the various practices. For example, the law stipulates that half of the members of a chamber should be practitioners of the non-conventional practices concerned offered by a professional association. Where there are several professional associations, as is the case for osteopaths, the possibility of presenting a member should be offered to all the professional associations.

### Key messages: the exercise of non-conventional medicine in Belgium

- The Colla law of 29 April 1999 is a framework law that governs, through a limited number of articles, the exercise of non-conventional medicine in Belgium.
- The purpose of the Colla law is to set rules in order to guarantee quality care for patients. This guarantee is provided essentially by a dual registration system: registration of non-conventional practices and the individual registration of practitioners.
- The Colla law contains a description of a non-conventional practice and considers homeopathy, chiropractic, osteopathy and acupuncture as such.
- A joint committee must be constituted. This committee is called upon to play a key role in the execution of the Colla law. In particular, it is tasked with issuing an advice on the general conditions governing the exercise of all non-conventional practices and the conditions that practitioners of non-conventional practices must satisfy for individual registration.
- A chamber is constituted for each of the recognised non-conventional practices. These chambers issue advices during the registration of a nonconventional practice or an individual practitioner.
- The Colla law provides for sanctions in the case of failure to comply with certain rules.
- The practitioners of a registered non-conventional practice are subject to multiple obligations.

# 5.1.5 The relationship between the Colla law and Royal Decree no. 78

# 5.1.5.1 General

Questions are being asked about the Colla law and its positioning in relation to Royal Decree no. 78.

A common denominator for the two texts is the similarity between the definitions of a non-conventional practice, namely 'the habitual practice of acts intended to improve and/or preserve human health, exercised according to the rules and conditions stipulated in this law' (Colla law) and 'the habitual performance by a person that does not satisfy all the conditions required by the first subparagraph of this paragraph of any act intended or presented as having the aim, with respect to humans, examining the state of health, or identifying illnesses and disorders, making a diagnosis, setting up or carrying out the treatment of a pathological, physical or mental condition, real or assumed, or vaccination', which is the definition of the (il)legal practice of medicine contained in Royal Decree no. 78. This definition is so broad that it also covers non-conventional practices<sup>78</sup>.

In its advice concerning the bill for the proposed Colla law, the legislation section of the Council of State believed that the description of a non-conventional practice was so broad that it covered acts that, by virtue of the laws in force, must be considered as forming part of the practice of medicine so that these practices were also governed by Royal Decree no. 78. The Council of State also thought that the non-conventional character of practices is such that they are exercised in accordance with the rules and conditions stipulated in the Colla law, in such a way that the practitioner of such practices has the choice: either the acts in question are performed in accordance with the provisions of the Colla law, or in accordance with the provisions of Royal Decree no. 78. In the former case, the practitioner exercises a non-conventional practice, in the second a conventional practice. The Council of State considers that a strict distinction is therefore established between conventional practices and non-conventional practices.

This raises the question of whether it is possible for a person to exercise at the same time a conventional and a non-conventional practice. The Colla law does not exclude this possibility.

## 5.1.5.2 In practice: the exercise of a non-conventional practice by a doctor

According to the Colla law, any person who exercises one of the registered non-conventional practices or who performs regularly acts forming part of this practice, without being individually registered, is punishable. This raises the question of whether a doctor is required to obtain individual registration in order to be able to exercise a non-conventional practice.

According to the legislation section of the Council of State, doctors exercising a non-conventional practice have the choice, when they perform the acts in question, of complying with (1) the provisions of the Colla law or (2) the provisions of Royal Decree no. 78. In the former case they are exercising a non-conventional practice and in the latter a conventional practice <sup>86 no. 1714/7</sup>.

A doctor can therefore exercise a registered non-conventional practice in accordance with the Colla law. In such a case, the doctor is clearly required to comply with the provisions of this law, and in particular the obligation of individual registration. If the doctor performs medical acts, he is also required to comply with the provisions of Royal Decree no. 78. This obligation is explicitly stipulated in the Colla law, which states that the provisions of Royal Decree no. 78 apply fully to the practitioners of registered non-conventional practices as mentioned in Royal Decree no. 78 in articles 2, 3, 21bis, 21quater and 22 (namely doctors, dentists, physiotherapists, nurses and paramedical personnel), provided that it concerns prerogatives granted to them by, or by virtue of, Royal Decree no. 78<sup>78</sup>.

Incidentally, a doctor wishing to exercise a non-conventional practice can opt not to get registered. Non-conventional practices are also covered by the broad definition of medicine in Royal Decree no. 78. From a legal standpoint, this means that the respective doctor is not strictly exercising a registered non-conventional practice, because he does not comply with the requirements of the Colla law<sup>78</sup>. In such a case doctors are nevertheless required to continue to take all normal precautions and refrain from performing medical acts for which they have insufficient knowledge<sup>87</sup>.

Finally, doctors may also exercise a registered non-conventional practice that (hypothetically) does not involve the practice of medicine. In such a case, only the Colla law would apply and the doctor would be required to obtain individual registration. Since Royal Decree no. 78 does not apply in this scenario, the doctor would not be performing medical acts. It is probable that the King, on the basis of the Colla law and on the advice of the joint committee, would declare one or more of the provisions of Royal Decree no. 78 applicable, in particular to doctors for acts not forming part of their prerogatives in or by virtue of Royal Decree no. 78<sup>78</sup>.

# 5.1.5.3 In practice: the exercise of a non-conventional practice by a non-doctor

Because of the broad definitions in the Colla law, certain acts classified exclusively as (conventional) medicine can now also be performed by non-doctors. Note however that this possibility is restricted to non-conventional practices, in accordance with the rules and conditions in force<sup>87</sup>.

In principle, it was intended to remove non-conventional practices from the field of application of Royal Decree no. 78. The King would still have had the option of extending the sanctions stipulated in Royal Decree no. 78 in the case of the illegitimate exercise of a profession to the practitioners of non-conventional practices<sup>78</sup>.

The Colla law also respects the monopoly of doctors, as seen in the obligation on non-doctors to obtain from their patients, in principle before the start of the non-conventional treatment, a recent written diagnosis concerning the symptoms, written by a doctor, on pain of being fined. Patients have the right not to consult a doctor in advance and to contact a non-doctor practitioner of a non-conventional practice directly. In this case, a written declaration by the patient must be attached to the record and the non-doctor practitioner will diagnose. In addition, practitioners of non-conventional practices are also required not to take into account the diagnosis of the doctor if they believe that this diagnosis is incorrect. They are not allowed to invoke the diagnosis of a doctor to escape their own responsibilities. Each intervening party will be deemed to be responsible for their share of the prejudice<sup>87</sup>.

# Key messages: the relationship between the Colla law and Royal Decree no. 78

- The description of the practice of medicine in Royal Decree no. 78 is so broad that it also covers non-conventional practices.
- Doctors exercising a non-conventional practice have two options. They can choose to exercise a non-conventional practice, in which case they must comply with the provisions of the Colla law, or they can choose to exercise a conventional practice, in which case they must comply with the provisions of Royal Decree no. 78.
- In accordance with the Colla law, a practitioner of a non-conventional practice may only provide a treatment for the patient after having received a recent diagnosis concerning the complaint, drawn up in writing by a doctor (unless the patient decides not to consult a doctor in advance).

# 5.1.6 The consequences of the (non-)conventional exercise of healthcare

# 5.1.6.1 Performing a diagnosis

In Belgium, only the holders of a doctor's diploma or a dentistry licence are authorised to perform a diagnosis and prescribe a treatment. They have systematic therapeutic and diagnostic freedom.<sup>75</sup> To make their diagnosis and choose the therapy they can therefore use the means that they deem suitable, including non-conventional practices. Practitioners that are not holders of such a diploma and perform diagnoses or choose therapies on a regular basis are then guilty of the illegal practice of medicine, which is punishable as a crime.

# 5.1.6.2 The application of the law of 22 August 2002 concerning the rights of patients

The law of 22 August 2002 concerning the rights of patients (hereafter the patients' rights act, published in the Belgian Official Journal on 26 September 2002), applies to all legal contractual and non-contractual relations under private and public law concerning healthcare dispensed to a patient by a professional practitioner.

The term 'professional practitioner' used in the patients' rights act refers to the practitioners mentioned in Royal Decree no. 78, as well as the professional practitioners of a non-conventional practice covered by the Colla law.

Although the patients' rights act clearly intends to apply to the practitioners of a non-conventional practice, this is never the case in practice. We have to wait for the entry into force of the Colla law for such practitioners to be also required to respect patients' rights under the terms of this law. In the absence of implementing orders, the main provisions of the Colla law have not yet entered into force. As soon as the key provisions of the Colla law enter effectively into force, the law of patients' rights will apply (automatically) to these professional practitioners. As a result, the practitioners of a non-conventional practice will also have to comply with the principles of the law of patients' rights, such as the right to the provision of quality services, to information on their state of health, to well-informed, free and prior consent, to refusal or retraction of such consent, to correctly updated individual records, to respect for privacy, etc.

# 5.1.6.3 The application of the law concerning compensation for damages resulting from healthcare

In its current form, the law of 31 March 2010 concerning compensation for damages resulting from healthcare (publication in the Belgian Official Journal of 2 April 2010) establishes the principle of compensation for prejudice resulting from the dispensation of healthcare and resulting from an act engaging the responsibility of a healthcare provider, or from a medical accident not engaging responsibility. In the latter case patients can obtain compensation from the medical accidents fund. The law provides for a series of exceptions, such as experiments or non-reimbursed aesthetic interventions. In some case the fund will not intervene further in the case of negligence on the part of the healthcare provider, for which the latter can be held responsible.

Under the law, the concept of 'healthcare' is understood in its broad sense. It is defined as the services dispensed by a healthcare provider in order to promote, determine, conserve, restore or improve the state of health of the patient or to provide end-of-life support. The definition of 'healthcare providers' is also very broad, including both professional practitioners and healthcare institutions. 'Professional practitioners' covers not only traditional professional practitioners (doctors, dentists, physiotherapists, pharmacists, etc.), but also the practitioners of non-conventional practices, but only as from the time the law enters into force.

# 5.1.6.4 Reimbursement of treatments

In Belgium, all persons are required to be insured for basic conventional healthcare. Patients that benefit from this conventional healthcare will be reimbursed (totally or partially) in principle in the form of an intervention by the compulsory health insurance. However, when a patient benefits from non-conventional healthcare, no such intervention occurs. In practice, when the non-conventional healthcare provider has an National Institute for Health and Disability Insurance (NIHDI) registration number, there may be some intervention by the compulsory healthcare insurance (for example a doctor who is also a homeopath and treats a patient can declare a consultation to the NIHDI)<sup>88</sup>.

Patients are nevertheless at liberty to choose alternative treatments. Each individual has a free choice of therapy. However, the compulsory health insurance does not reimburse these alternative treatments. Some healthcare providers nevertheless offer reimbursement of certain alternative treatments via a complementary free insurance.

Because patients are increasingly resorting to non-conventional medicine, the sickness funds, in response to the demands of their members, are starting to reimburse (partially) certain forms of non-conventional medicine. As the sickness funds are free institutions, they can take decisions concerning complementary insurance without in principle having to request the consent of the state, apart from the sickness fund audit service. It is therefore possible for them to adapt their services to changes in the expectations of their members. In this case, such an adaptation has already taken place with the incorporation of certain non-conventional practices into general complementary insurance. The majority of the sickness funds limit such intervention to a number of non-conventional practices, with certain conditions attached to each of these practices (such as a ceiling on reimbursements)<sup>88</sup>.

Detractors of this approach argue that by reimbursing alternative medicines the sickness funds and insurance companies are acting as trading companies, placing themselves above the law and giving a false signal to the public. Reimbursement of this type could induce patients to opt for non-regulated and non-recognised treatments, the usefulness of which is very limited and the risks far from negligible<sup>89</sup>.

The debate on the advisability of state and/or sickness fund intervention in alternative medicines was reignited in January 2004, after some thirty sceptics absorbed an overdose of homeopathy (30 ml of a dilution C30 (I per 10<sup>60</sup> of snake venom, arsenic, belladonna, dog milk or extract of cockroach) in the University of Ghent. The purpose of this pretended suicide using a homeopathic product was to prove that homeopathic medicines do not contain active substances, as well as to challenge the sickness funds, which reimburse non-certified medicines on the basis of 'customer satisfaction' and not their 'proven effectiveness'.

# 5.1.6.5 Training

Acupuncture is now taught in certain faculties of medicine. The Brussels Free University introduced a full training course in osteopathy in 2006.

In Flanders it is possible to follow a training course in osteopathy in non-subsidised private institutes (such as the International Academy of Osteopathy (IAO) in Ghent, or the Flanders International College of Osteopathy (FICO) in Antwerp). Since the 2004-2005 academic year, the ULB has also offered training in osteopathy. This training is dispensed in the context of the *Institut des Sciences de la Motricité* (Institute of Motor Control Sciences) in the form of a complementary master's degree. This training is reserved for the holders of a diploma in motor control sciences, with a specialisation in osteopathy. It is dispensed by professors of the faculties of medicine and motor control sciences, as well as by osteopaths with a diploma (DO) for the practical exercises.

The training is subdivided into three years of baccalaureate, followed by two years of a master's, then a year of post-master's. This official university training, incidentally the first in Europe, could be offered thanks to the decree of 31 March 2004 of the French-speaking community defining higher education, favouring its integration into the European space for higher education and the refinancing of universities (Belgian Official Journal of 18 June 2004). This decree falls within the framework of the Bologna European reforms. Although it is possible to obtain a diploma in osteopathy from the ULB, nothing changes the fact that the exercise of this practice has not yet been recognised and that, in the strict sense, it could be seen as the illegal practice of medicine.

# 5.1.6.6 Liability for the exercise of a non-conventional practice

As long as the Colla law has not been executed, many questions continue to be asked concerning the resulting liability. We often wonder to what extent the practitioners of non-conventional practices have acted in the field of medical practices. This can be illustrated with examples.

On 9 June 2009, the correctional court of Bruges had to judge a physiotherapist who practiced acupuncture. The Belgian Association of Acupuncturist (referred to as the Association professionnelle des Médecins-Acupuncteurs de Belgique in the judgement) had lodged a civil complaint concerning the alleged illegal practice of medicine/pharmacy. In its judgement, the president referred to a decree of the Court of Cassation of 20 June 1990, in which the court considered that the practice of acupuncture qualified as performing a medical act (see below). The president also considered that acupuncture formed part of non-conventional practices of medicine and that, in accordance with the Colla law, it did not fall within the scope of Royal Decree no. 78 in that it was exercised in accordance with the rules and conditions in the Colla law. Since the law had not yet come into force, an acupuncturist was not in a position to comply with these conditions, with the result that only doctors are authorised legally to perform acts that are considered by the Colla law as acts of a non-conventional practice. The acupuncturist in question was therefore found guilty of the illegal exercise of the profession.

Nevertheless, the correctional court acquitted the acupuncturist in question. The president stressed that the use of non-conventional medicines was part of social reality, as confirmed by the Colla law and the attitude taken by several sickness funds. The president also pointed out the resulting contradiction between acupuncturists who had undergone serious training and were holders of an acupuncture diploma and members of a recognised professional organisation, but illegally practised medicine, and doctors who were authorised to perform acupuncture, in application of their therapeutic freedom, but did not have the benefit of training for this purpose. This situation prompted the president to take the following attitude: an acupuncturist could choose not to treat the patient that consulted him because of his competence in the field of acupuncture; in doing so, the acupuncturist would contravene his professional responsibility, which insists that the patient should be given the required assistance, thus committing an act punishable by law for omitting to assist a person in danger (article 422bis of the penal code). The obligation to provide quality care could oblige the acupuncturist to administer acupuncture treatment, while such treatment constitutes an offence against Royal Decree no. 78, based on the current situation. The court judged that for the accused there could be a justifying emergency situation, following the paradoxical finding where the accused contravened Royal Decree no. 78 (because of the absence of executory decisions) in order to preserve a greater legal value, namely the dispensation of quality care to patients. Meanwhile, the public ministry has appealed against this judgement. The judgement of the court of appeal was not known at the time of completing this study.

In another case, the Antwerp court of appeal confirmed on 25 June 2010 the acquittal of a defendant, for similar acts, pronounced by the correctional court of Turnhout on 13 February 2009. In this case it was a physiotherapist who, after having followed a training course in acupuncture, began to exercise this practice. He was also summonsed for the illegal practice of medicine, namely practicing acupuncture as a non-doctor. The president of the correctional court first stated that the accused exercised a completely separate medical profession as a physiotherapist, which authorised him to perform certain acts listed by the law without becoming guilty of the illegal practice of medicine. These include certain medical acts that can only be performed in consultation with the attending physician. The president went on to state that the exercise of acupuncture did not form part of the conventional practices referred to in Royal Decree no. 78, but fell into a legal void because of the non-execution of the Colla law. The president also pointed out that the law placed no explicit prohibition on physiotherapists practising acupuncture, and that it appeared that the legislator, through the Colla law, also intended to authorise physiotherapists to exercise non-conventional practices under certain conditions. The president also referred to the Royal Decree of 10 February 2003, concerning recognition of the professional association of acupuncturists. The fact that non-doctors are members of this association prompted the president to deem that this recognition by the public authorities should be considered as recognition of the legitimacy of the practice of acupuncture by non-doctors. The president also deemed that a physiotherapist who practiced acupuncture should comply, for this practice, with the restrictions and obligations applicable to a conventional practice, precisely because of the current legal void. Considering that the defendant had undergone serious training in acupuncture and that he was a member of a recognised professional association, and also considering that he had in this case provided proof of the fact that he had always acted in consultation with an attending physician, the president judged that the defendant, in the absence of legal execution conditions, had complied with all the currently applicable legal obligations for practicing acupuncture in the context of a medical profession, and that he had respected all the conditions and restrictions imposed on physiotherapists by Royal Decree no. 78. However, the president referred to an interpretation of the Court of Appeal in Ghent in its ruling of 28 June 2000, where a physiotherapist was judged guilty of the illegal practice of medicine when, on the basis of his knowledge of Chinese medicine and acupuncture, he made his own diagnosis and dispensed treatment on this basis. In the case brought before the Ghent court of appeal, the accused was declared guilty of the illegal practice of medicine, but was given a suspended sentence because of the serious training he had followed and the dilatory attitude of the legislator. (Ghent, 28 June 2000, T. Gez. 2001-02, 195).

Recent jurisprudence therefore does not automatically consider the exercise of a non-conventional practice without being a doctor as the illegal practice of medicine. It should however be noted that the courts do not generally give an acquittal, because there is no question in these cases of the illegal practice of medicine (which it is), but rather a 'bypass', such as the long-standing existence of a legal void, or the theory of THjustification by a state of necessity. It concerns legal concepts under ordinary penal law, which therefore have no fundamental link with Royal Decree no. 78.

On the other hand, the oldest jurisprudence takes this view. Note in particular the sentence of 14 September 1999 of a Chinese doctor by the court of first instance of Ghent, for the illegal practice of medicine and pharmacy. This practitioner was a Chinese doctor operating in Belgium and the Netherlands, practicing mainly acupuncture, phytotherapy and the administration of herbal remedies. Although he had been trained as a doctor in China, he had not obtained recognition of his diploma in Belgium because of the duration and complexity of the procedure. For this reason he was not authorised to perform in Belgium acts classified as medicine or pharmacy. In his defence, he invoked the argument that he was not practicing medicine.

This argument was dismissed because both doctrine and jurisprudence in Belgium consider the practice of acupuncture as forming part of medicine. In accordance with a decree of the Court of Cassation of 20 June 1990, Royal Decree no. 78 must not be interpreted in a restrictive sense and it also covers alternative medicine<sup>90</sup>. Although the Chinese doctor invoked the Colla law on the subject of acupuncture (not yet published at the time, but already promulgated and published by the King), the court judged that he could not invoke it because he was not registered as a practitioner of acupuncture. The same applies at the present time because of the absence of executory decisions relating to the Colla law.

The courts have also ruled on the responsibility of a homeopath who carried out this practice in the Netherlands where he treated Belgians. One of them brought this Belgian homeopath before the Belgian courts. Since the homeopathic treatment had been administered in the Netherlands, the case was governed by Dutch law. On 16 February 1998, the Antwerp court of appeal recognised the specificity of a homeopath in that a patient that chooses to contact such a non-conventional practitioner does so in full awareness and cannot expect the same criteria as a traditional doctor, and that the patient to some extent accepts the risk. This is not strictly speaking an acceptance of the risk, but a simple application of the rules of responsibility, namely checking the references of a normally prudent non-conventional homeopath placed in the same context<sup>91</sup>.

In the 1980s a number of osteopaths were summonsed for the illegal practice of medicine. Most of them (mainly physiotherapists) were acquitted. An osteopath was however sentenced on 15 May 1985 by the court of first instance in Namur. Since the defendant did not have a medical diploma, the court tried to determine whether or not he had performed medical acts. To do this, the president made a comparison between (certain) osteopathic treatments and medicine and concluded that the acts performed on a regular basis by the accused should be considered as medical treatments. In this case, the defendant was sentenced for the illegal practice of medicine.

# 5.1.6.7 Homeopathic medicines

A homeopathic medicine is defined by law as any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles. <sup>92</sup>

In Belgium, homeopathic medicines can solely be sold at the pharmacy. All homeopathic medicines that are put on the market in Belgium must have been notified in 2003 to the Federal Agency of Medicinal and Health Products (FAGG/AFMPS) and a notification number must be mentioned on the labelling. Magistrals delivered by pharmacists are not submitted to notification. The notification phase is a one shot phase, inserted as an intermediary phase awaiting the registration or authorisation of every homeopathic medicine. According to the notification procedure information related to the quality, the use, the producer etc. needs to be provided. This does, however, not imply any evaluation of these topics. All the manufacturers and distributors of notified homeopathic medicinal products must be authorised and follow requirements, in particular the Good manufacturing practices and good distribution practices. The requirements of the European pharmacopoeia or of other pharmacopoeia officially used in a member state must also be followed. As all the pharmaceutical companies, they are submitted to inspections on a regular basis.

Particular procedures have been set up before homeopathic medicines can enter the market. 93, 94 There is a simplified procedure (registration) for homeopathic medicines for oral or external use, where no specific therapeutic indication is mentioned on the label or in the information concerning the medicine in question, and where its dilution level is such that the safety of the medicine is guaranteed. During this procedure, the Commission for homeopathic medicines for human and veterinary use (hereinafter called as 'the Commission') assesses the quality, safety and the justification for homeopathic use. The justification of a homeopathic medicine is based on references to medical literature including clinical verifications and trials with healthy persons. It is important to note that no particular therapeutic indication can be accepted via this procedure. This has to be noted on the label of the medicine.

Homeopathic medicines that do not meet the conditions for the registration procedure are subject to the marketing authorisation procedure. The assessment includes quality, safety and homeopathic use in accordance with the principles and specificities of homeopathic medicine. For the evaluation of homeopathic use, the required level of clinical evidence needs to be proportionate to the level of the presented therapeutic indication. This implies that, where appropriate, the Commission can require randomised trials versus placebo<sup>5</sup>. With regard to the above mentioned procedures guidance has been published by the European Medicines Agency<sup>95</sup>, by the Heads of Medicines Agencies<sup>96</sup> (these documents solely concern the simplified procedure for unicist homeopathic medicines) and the Belgian Agency for Medicines and Health Products<sup>97</sup> In September 2010, the first marketing authorisation was granted to the homeopathic medicine, Oculo-Heel®. It was concluded that this homeopathic medicinal product is conform to the requirements of the law and the Royal Decree of 14/12/2006. 93, 94 This medicinal product is not submitted to prescription. The authorised therapeutic indication by the Minister or its delegate, on basis of the advice of the commission for homeopathic medicinal products for human and veterinary use corresponds to the following :"Homeopathic medicinal product containing active substances (dilution or trituration of stocks) traditionally used for irritation of eyes".

During the evaluation of homeopathic medicinal products, the commission for homeopathic medicinal products for human and veterinary use could formulate advice requiring medical prescription for some homeopathic medicinal products taking into account some criteria such as the character of the indication and the need of a medical doctor's supervision.

Information on the content of the procedures was provided by personal communication of the FAGG/AFMPS

# Key messages: The consequences of the (non-)conventional exercise of healthcare

- Only the holders of a medical diploma or a dentistry licence are authorised to perform a diagnosis and prescribe a treatment.
- The law of 22 August 2002 concerning patients' rights will only apply to the exercise of non-conventional practices when the Colla law has been executed.
- The same applies to the application of the law of 31 March 2010 concerning compensation for damages resulting from healthcare.
- Certain sickness funds reimburse certain forms of alternative treatments.
- Although it is often a question of organised training, no non-conventional practice has been recognised to date, so the exercise of these practices can be considered as the illegal practice of medicine.
- Although many practitioners of a non-conventional practice have already been sentenced for the illegal practice of medicine, the courts seem increasingly disinclined to hand down sentences.

# 5.1.7 The exercise of non-conventional medicine in the European context

# 5.1.7.1 Two concepts

Two concepts of healthcare coexist within the European Union<sup>98</sup>.

According to the *first concept*, only doctors are authorised to practice medicine, with a few exceptions (this concept applies to Belgium). In the countries that have adopted this approach, the demand for non-conventional medicines is so high that some tolerance is shown.

The second concept is based on the reverse principle and considers that any person who so desires can practice medicine, with the exception of certain acts that can only be performed by doctors.

Because of the coexistence of these two conflicting concepts, the European parliament is often confronted with the case of healthcare practitioners that are officially recognised in their own country, but condemned in another country for the illegal practice of medicine. The divergences in status and recognition procedures for nonconventional medicines within the European Union contravene the principles of the free circulation of persons and freedom of establishment (as guaranteed by the treaty governing the functioning of the European Union). A resolution was finally adopted in 1997 concerning the status of non-conventional medicine (OJ no. C-182, 16 June 1997, 0067), in which the European parliament asks the Commission to pursue the recognition of non-conventional medicines. This resolution comes out in favour of the recognition of non-conventional medicine, provided that the results of the study permit. On 11 June 1999, the Council of Europe also published a resolution on this subject (not binding on Member States) in which it calls for Member States to harmonise their regulations<sup>99</sup>.

'COST B4' was set up ("European Cooperation in the field of Science and Technology") to better consolidate the results of scientific studies of non-conventional medicines. This group has come to the conclusion that the key criterion for the choice of a therapy should be its effectiveness, attested preferably by double-blind randomised testing, while recommending also taking into account the satisfaction and welfare of the patient, for both conventional and non-conventional treatments. According to this group, the states should encourage studies of non-conventional treatments, while ensuring that such studies use rigorous methodologies<sup>89</sup>.

# 5.1.7.2 Proof of clinical effectiveness

In its report of 6 March 1997 on the status of non-conventional medicine, the European parliament deemed that it would be advisable to distinguish between the different nonconventional medicines. Clinical studies, an assessment of the results of treatments and other scientific or academic studies are required to analyse the facts and how they interrelate. According to the European parliament, this assessment should use methodologies suitable for the different medicines. However this approach tends to fall apart when their therapeutic effect cannot be certified by commonly accepted scientific methods. This is a somewhat controversial issue. It is therefore important to choose recognised methodologies and to define suitable validity criteria. Moreover, the European parliament is aware that it would be advisable to use a 'fluctuating range' of proofs and acceptability rather than a strict divide between scientific and non-scientific proof. Another element that needs to be considered is the fact that several nonconventional medicines already benefit from some form of official recognition in certain Member States and sometimes have a representative professional organisation at European level. Their effectiveness has been certified by various studies (limited scope), the results of which are generally convincing (for example chiropractic and homeopathy).

# Key messages: the exercise of non-conventional medicine in the European context

- Two concepts of healthcare coexist within the European Union.
- According to the first principle, only doctors are authorised to practice medicine.
- According to the second principle, any person who so desires can practice medicine, with the exception of certain acts, which are reserved for doctors.
- Proof of clinical effectiveness is important in order to distinguish between non-conventional practices.

# 5.1.8 Conclusion concerning the Belgian and European legal framework

# 5.1.8.1 The practice of conventional medicine in Belgium

The practice of conventional medicine in Belgium is governed by Royal Decree no. 78. By the 'practice of medicine' the law means the medical art, medicine, physiotherapy, nursing, the paramedical professions and midwifery. Each of these professions is governed by specific criteria.

# 5.1.8.2 The practice of non-conventional medicine in Belgium

The law of 29 April 1999 concerning non-conventional practices in the field of medicine, pharmaceuticals, physiotherapy, nursing and the paramedical professions defines a framework for recognition of the practice of (certain forms) of non-conventional medicine. The Colla law considers the practice of homeopathy, chiropractic, osteopathy and acupuncture to be non-conventional practices. This list is not restrictive and other non-conventional practices could be added.

The purpose of the Colla law is to guarantee quality care for patients. This guarantee is provided by a dual registration system. Firstly, each of the non-conventional practices must be registered (which is only possible if certain criteria are satisfied) and secondly, each practitioner of these disciplines must also be registered (satisfying various conditions).

The joint committee instigated by the Colla law is called on to play a key role in this field, notably by giving an advice concerning the general conditions applicable to the exercise of non-conventional practices.

Since this joint committee has not yet been formed, it is not in a position to play this key role, so the law cannot be executed and is therefore not yet in force.

# 5.1.8.3 The relationship between the Colla law and Royal Decree no. 78

Royal Decree no. 78 provides such a broad description of the practice of medicine that it covers the exercise of non-conventional practices.

Practitioners of non-conventional practices who are also doctors have the choice of exercising a non-conventional practice or a conventional practice. In the former case, they must comply with the Colla law, and in the latter with the provisions of Royal Decree no. 78. However, practitioners of non-conventional practices who are not doctors can only perform these practices after having received a recent written diagnosis from a doctor concerning the complaint.

# 5.1.8.4 The consequences of the (non-)conventional exercise of healthcare

Only the holders of a medical diploma or a dentistry licence are authorised to perform a diagnosis and prescribe a treatment.

The provisions of the law of patients' rights of 22 August 2002 and the law on healthcare compensation of 31 March 2010 can only be applied to practitioners of non-conventional practices when the Colla law has come fully into force.

As long as the Colla law is not fully applied, the practice of non-conventional medicine, by a non-doctor therapist is qualified as the illegal practice of medicine. Several practitioners of non-conventional practices who are not doctors have already been sentenced for this reason. It should however be noted that jurisprudence is tending increasingly towards acquittal, provided that certain conditions are satisfied (such as adequate training) and in the light of the failure to execute the Colla law. In addition, certain medical treatments that can also be practiced as alternative therapies can also be practiced legally by certain professionals such as physiotherapists.

# 5.1.8.5 The exercise of non-conventional medicine in the European context

Two concepts of healthcare coexist within the European Union. According to the first principle, only doctors are authorised to practice medicine. According to the second principle, any person who so desires can practice medicine, with the exception of certain acts which are reserved for doctors.

# 5.2 THE SITUATION IN THE NETHERLANDS, FRANCE AND THE UNITED KINGDOM

This chapter is common to the three reports on alternative medicines, as most of the issues are common to all non-conventional practices.

#### 5.2.1 Structure of the chapter

This chapter contains a brief presentation of the legal situation in the Netherlands, France and the United Kingdom.

# 5.2.2 Netherlands

#### 5.2.2.1 The legal situation

In 1865 the Netherlands promulgated the Wet op de Uitoefening der Geneeskunst (law on the practice of medicine, hereafter referred to as 'WUG'), which introduced an examination prior to becoming a doctor. This law makes a distinction between conventional medicine and non-conventional medicine, making the practice of conventional medicine by unauthorised persons punishable. The Dutch legislation tolerates alternative therapists. In the Netherlands, 'alternative' medicine is the opposite of 'conventional' medicine.

This monopoly of doctors was amended in November 1993 by the Wet Beroepen in de Individuele Gezondheidszorg (law concerning the individual healthcare professions, hereafter referred to as 'BIG'). In principle this law authorises anyone to provide medical care, with the exception of certain acts that can only be performed by practitioners specially authorised for this purpose by the BIG law.

These are acts that entail a substantial risk for the health of the patient if they are not carried out by a competent therapist (particularly surgery, obstetrics and anaesthesia). However a diagnosis can be performed by anyone. The freedom to practice medicine is offset by a penal counterweight: any person that harm's the health of another is punishable under the BIG law.

#### 5.2.2.2 The BIG law

The BIG law is partially a framework law. The main points governed by this law are registration of constitution and protection of certificates, the reserved acts (including the associated mission), disciplinary law and criminal law, specialities and the accreditation of foreign diplomas. Many of the modalities have to be finalised by 'general administration measures' (executory decisions), such as the training requirements, the fields of specialisation and the periodic registration system, as well as quality criteria. The legislation also entrusts a large number of issues to self-regulation by professional associations, within the framework defined by the law, such as the introduction of specialities<sup>100</sup>. Because Dutch law has also opted (partially) for a framework law, its implementation is subject to executory decisions. In the Netherlands this approach has also been onerous and has also been staggered over several years.

The principle of the BIG law is based on the registration of professional certificates and training certificates, with a fundamental distinction between two categories. The first category is that of 'heavy regulation' (literal translation) and covers doctors, dentists, psychologists, psychotherapists, physiotherapists, obstetricians and nurses (article 3). For each of these professions, the BIG law governs the level of competence and the requirements in terms of training. The BIG law also contains provisions governing the introduction of specialities, in close consultation with the representative professional organisations.

The second category is that of 'light regulation', which applies to the paramedical professions, based on the principle that training must satisfy quality criteria (article 34). Only people that have followed successfully the training imposed or recommended by the minister can use the certificate issued after such training<sup>101</sup>.

The legal authorisation to hold a certificate protected by the law is granted via a substantive registration, which also acts as protection of the certificate under the 'heavy regulation' of the professions mentioned in article 3, and via protection of the training certificate under the 'light regulation' mentioned in article 34. The fact of having successfully completed the required training gives the right to inscription in the BIG register (comparable to the INAMI in Belgium) under the terms of article 3 or, for the protection of the training certificate, under article 34. Inscription in the article 3 register authorises the person that followed the training to hold the related certificate. The training certificate for the professions in article 34 is protected and can be used without prior registration. Non-registered persons are not authorised to hold the certificate. The illegitimate use of a protected certificate or a similar title is punishable by law<sup>100</sup>.

A corollary of inscription in the BIG register is the authorisation to evolve independently in the field of reserved acts, provided that such acts are considered by the law to form part of the profession in question. Inscription is also equivalent to formal recognition of the competence of the person in the domain specific to the profession (or specialisation). The fields of competence are described for each group of professions, which gives particular importance to the issue of public information. The field of competence also intervenes in disciplinary law (which only applies to therapists registered in the context of article which does not allow the practitioners of an 'article 34' profession to evade the legal obligation to provide suitable care) and the penal provisions. The respective fields of competence of doctors, dentists, pharmacists and nurses are described briefly in the BIG law. For the other 'article 3' professions and for the 'article 34' professions, the field of competence is governed by the executory decisions, taking into account the fact that these fields are less fixed and more likely to evolve. The authorisation to perform reserved acts is the legal restriction in relation to the professional practice of competent persons.

The competence to perform reserved acts can be used independently in practice, provided that the competence was acquired by experience. If a person is authorised, but not competent, to perform reserved acts, that person can give a prescription for the treatment.

Assessment of competence is entrusted to the practitioner of the profession in question, or to the professional association<sup>100</sup>.

#### 5.2.2.3 Evaluation of the BIG law

As for alternative medicine, Dutch legislation has adopted the principle of self-regulation for improving healthcare quality and public information by alternative practitioners. The practitioners of alternative medicine are not covered by the BIG law and have no official recognition. There is no registration mechanism for alternative medicines<sup>91</sup>.

Because of the BIG law, the position in society of the associations representing alternative medicines has considerably changed in several ways, especially with the disappearance of the concept of the *unauthorised practice of medicine*. Moreover, the BIG law governs exclusively what the law terms 'qualified persons', tipping the scale too far in the direction of freedom of choice for citizens, to the detriment of safety. In addition, control by public bodies of non-conventional (alternative) practitioners is considered inadequate and the public ministry would not sufficiently pursue litigation. Other criticisms: the penal sanctions are considered to be too heavy, the plaintiff is not sufficiently protected and the quality of care is too dependent on the approach chosen by the professional association<sup>100</sup>.

Many criticisms have also been levelled against the attitude of the public authorities, which are more or less neutral concerning alternative medicine. Some believe that the public authorities should draw up without delay a specific policy concerning the alternative professions mentioned in article 34. This would provide sufficient clarity in the meantime concerning the criteria to be used<sup>100</sup>.

#### Key points: the situation in the Netherlands

- In principle the BIG allows anyone to provide medical care, with the exception of certain 'reserved' acts that can only be performed by the professional practitioners authorised by the BIG law.
- The BIG law is partially a framework law which governs various important matters. Many other modalities are nevertheless left to self-regulation by the professional organisations.
- The BIG law is based on the principle of registration of professional certificates and training certificates, and makes a distinction between two categories, each subject to specific rules.

#### 5.2.3 France

# 5.2.3.1 General

As in Belgium, French law considers only qualified doctors that can practice medicine. As a result, the exercise of alternative treatments is reserved for doctors, which has led to a paradox in France, where certain doctors that only have a fragmentary knowledge of alternative treatments are authorised to use them, while these practices are prohibited for non-doctors that have followed proper training in alternative therapies. If this prohibition is flouted, non-doctors are open to litigation. <sup>100</sup>

Notwithstanding these principles, France shows a degree of tolerance, as we shall see below.

# 5.2.3.2 Homeopathy

In France, homeopathic medicines obtained by medical prescription are reimbursed by the sickness fund, and have been since 1948. This is a peculiar situation in that homeopathy is not recognised by French law because it is not backed by any diploma 102 and the acts performed by homeopaths are not eligible for differentiated reimbursement 98.

# 5.2.3.3 Osteopathy and chiropractic

In March 2000, the minister Kouchner set up a commission tasked with drafting criteria for the official recognition of osteopathy and chiropractic. These criteria are found in article 75 of the law of 4 March 2002 concerning the rights of the sick and the quality of the health system. According to article 75 of this law, the use of an osteopath or a chiropractor is reserved for the holders of a diploma issued by establishments and institutes approved by the Ministry of Health, and according to the modalities fixed by decree. The programme and duration of such training (at least 3 520 hours), and the examinations that sanction them, are also fixed by a regulation.

An equivalent official qualification must be given to foreign diplomas, according to the modalities fixed by decree. Article 75 also stipulates that the practitioners of these disciplines are subject to an obligation of ongoing training, the modalities of which must also be defined by decree. The High Authority for Health (Haute Autorité de Santé) was given the task of drafting and validating the recommendations for good practices, as well as drawing up a list of good practices that should be taught by the training establishments and institutes. Article 75 also stipulates publication by decree of a list of acts that can be performed by osteopaths and chiropractors, as well as the conditions governing these practices. These practitioners can only perform therapeutic acts after inscription in the list.

Meanwhile, several executory decisions concerning osteopathy have been taken. These include decree 2007-435 of 25 March 2007 concerning the acts and conditions of exercise of osteopathy and various orders of 25 March 2007 concerning the practice of osteopathy in France. These provisions define the objectives of osteopathy, the manner of achieving these objectives and acts that are authorised or not. Only (1) doctors, midwives, masseur-physiotherapists and nurses with a university diploma (D.U.) or an interuniversity diploma (D.I.U.), (2) the holders of a diploma in osteopathy issued by a recognised establishment and (3) holders of an authorisation to practice osteopathy or use the title of osteopath issued by an authorised body, can use the title of practitioner of osteopathy. Osteopaths must also register their certificate. The training modalities and the approval of osteopathy institutes are governed by the orders of 25 March 2007.

The French universities offer two types of diploma: national diplomas that are subject to authorisation by the ministry, and diplomas delivered under the sole responsibility of the university independently and following approval by the board of directors. A university diploma (D.U.) where the university teaches the subject in question and the interuniversity diploma (D.I.U.) where several universities teach the same subject<sup>102</sup>.

# 5.2.3.4 Acupuncture

Acupuncture has been recognised since 1950 by the *Académie de Médecine française*. It can be practiced legally, but only by doctors<sup>102</sup>. When the intervention is on a medical prescription, it is even partially reimbursed by the social security. In France, acupuncturists are non-doctors and are not recognised. If they practice acupuncture, they may be found guilty of the illegal practice of medicine.

For several years there has been a D.I.U. in acupuncture for doctors. The teaching and good practices of acupuncture are regulated in this way. According to the *Ordre français* des *Médecins*, only doctors with a diploma in acupuncture can make use of this skill. Since November 2009, the faculty of medicine at Paris Sud XI has offered a D.U. in 'Oriental medical acupuncture'. This training is open to doctors, veterinarians and midwives.

#### 5.2.3.5 Reimbursement

In France also, various sickness funds reimburse non-conventional practices. These reimbursements are often limited to a given number of sessions. In some cases reimbursement is offered as part of complementary insurance. Recognition of the diploma by the sickness fund is often one of the reimbursement conditions <sup>102</sup>.

## Key points: the situation in France

- Only qualified doctors can practice medicine. The use of alternative therapies is restricted to doctors.
- Although homeopathy is not recognised by the law, homeopathic medicines are reimbursed by the sickness funds under certain conditions.
- France has already taken various initiatives for the recognition of osteopathy and chiropractic.
- In France, acupuncture is recognised by the Académie de Médecine and can be practiced legally by doctors.

# 5.2.4 United Kingdom

#### 5.2.4.1 Common law versus self-regulation

In British law, non-conventional medicines are referred to as complementary and alternative medicines (CAM).

In the United Kingdom, under Common Law (case law), any non-doctor can offer an alternative therapy, provided that he or she does not claim to be a doctor, does not practice a protected discipline (dentist, midwife or veterinarian for example) and does not prescribe medicines available exclusively by medical prescription<sup>103</sup>. These therapists cannot claim to be capable of curing certain diseases (such as cancer, tuberculosis or epilepsy) or advertise their services<sup>104</sup>. Nevertheless, they can treat these diseases.

Because the United Kingdom does not prohibit the practice of alternative medicines, there are only a few stipulations and obligations, so practitioners can make a personal choice and follow their own programme<sup>103</sup>.

Despite this context specific to the United Kingdom, there have been calls for regulation. The Health Act of 1999 stipulates that CAM practitioners could be regulated without having to undergo the long procedure of a parliamentary law, as was the case for osteopathy and chiropractic (see below). The majority of CAM practitioners nevertheless prefer self-regulation (freely consented) to legislation. This has also been widely opposed because of the great liberty offered by Common Law<sup>104</sup>.

In 2000, the House of Lords published a report on CAMs. In this report, CAMs are subdivided into three main groups, the first of which is professionally organised alternative practices. Acupuncture, chiropractic, osteopathy and homeopathy form part of this group <sup>103</sup>. The report also makes recommendations concerning training, research and development, the dissemination of information, etc. <sup>104</sup>.

# 5.2.4.2 Osteopathy and chiropractic

Despite Common Law in the United Kingdom, osteopathy and chiropractic have taken a different route. These two disciplines have undergone the lengthy journey towards self-regulation, after which they will benefit from a special legal status under new legislation.

Osteopathy was given legal status under the Osteopaths Act 1993. This act governs the practice of osteopathy in terms of the registration of accredited osteopaths, osteopathic training and the conditions governing the profession. The regulatory body set up under the law is the General Osteopathic Council.

Any person wishing to practice osteopathy in the United Kingdom must be registered by this body after following an approved training course.

Chiropractic is governed by the Chiropractors Act 1994. This law regulates chiropractic in terms of the registration of recognised chiropractors, chiropractic training and the conditions governing the profession. The regulatory body set up under the law is the General Osteopathic Council. Any person wishing to practice chiropractic in the United Kingdom must be registered by this body after following a recognised training course.

# 5.2.4.3 Homeopathy

Homeopathy was recognised in 1950 by the Faculty of Homeopathy Act. This 'Faculty' trains doctors, veterinarians, dentists and midwives in homeopathy and is officially recognised by the state as a homeopathy training institute <sup>105</sup>.

No special registration applies to other homeopaths, i.e. practitioners who are not doctors, veterinarians, dentists or midwives. There are professional organisations of homeopaths, which require their members to be properly insured and to comply with the Code of Professional Ethics<sup>106</sup>.

# 5.2.4.4 Acupuncture

The report published by the House of Lords in 2000 recommended that practitioners of phytotherapy and acupuncture should opt for statutory regulation in the same way as osteopathy and chiropractic<sup>104</sup>. Subsequently proposals along the lines of such regulation have been drawn up by the Department of Health. The main purpose of this regulation is to protect patients by setting criteria for training and competence. To date, these proposals have not been transposed into legislation.

#### 5.2.4.5 Other CAM practices

As for other CAM practices, the British public authorities encourage practitioners to self-regulate and have no intention of intervening through legislation. The public authorities apply the principle that unregulated CAM practitioners must set the criteria and modalities for their practices. Nevertheless, there is a Complementary and Natural Healthcare Council, within which a register has been opened for the registration of practitioners that comply with certain standards, have followed some training and are adequately insured<sup>107</sup>.

#### 5.2.4.6 Reimbursement

As a general rule, the costs of non-conventional medicines are not reimbursed by the National Health Service<sup>108</sup>. The United Kingdom is however the only country in Europe to have several public hospitals that offer (exclusively) alternative medicine services (Glasgow, London, Liverpool, Bristol and Tunbridge Wells)<sup>106</sup>. These services are reimbursed by the National Health Service. Moreover, various individual insurance policies help to pay the cost of an alternative therapy, often on condition that the acts in question are performed by an accredited practitioner<sup>108</sup>.

# Key points: the situation in the United Kingdom

- Under common law, any non-doctor can offer alternative therapies, provided that they do not claim to be a doctor and do not practice a protected discipline. Such persons are not allowed to claim that they can cure diseases. However, they can treat diseases.
- Osteopathy and chiropractic have been given legal status in law.
- Homeopathy has been recognised by the Faculty of Homeopathy Act. This faculty trains doctors, veterinarians, dentists and midwives in homeopathy.
- Acupuncture should also benefit from a legal status under the law, but this process has not yet been finalised.
- As for other alternative therapies, the public authorities recommend that practitioners should self-regulate their profession.

# 5.2.5 Conclusion on the situation in the Netherlands, France and the United Kingdom

#### 5.2.5.1 The situation in the Netherlands

In principle the BIG allows anyone to provide medical care, with the exception of certain 'reserved' acts that can only be performed by the professional practitioners authorised by the BIG law.

The BIG law is partially a framework law which governs various important points. Many other modalities are nevertheless left to self-regulation by the professional organisations. The BIG law is based on the principle of registration of professional certificates and training certificates, and makes a distinction between two categories, each subject to specific rules.

# 5.2.5.2 The situation in France

Only qualified doctors can practice medicine. The use of alternative therapies is restricted to doctors. France has already taken various initiatives for the recognition of osteopathy and chiropractic. In France, acupuncture is recognised by the *Académie de Médecine* and can be practiced legally by doctors.

# 5.2.5.3 The situation in the United Kingdom

Under common law, any non-doctor can offer alternative therapies, provided that they do not claim to be a doctor and do not practice a protected discipline. Such persons are not allowed to claim that they can cure diseases. However, they can treat diseases.

Osteopathy and chiropractic have been given legal status in law. Homeopathy has been recognised by the Faculty of Homeopathy Act. This faculty trains doctors, veterinarians, dentists and midwives in homeopathy. Acupuncture should also benefit from a legal status under the law, but this process has not yet been finalised. As for other alternative therapies, the public authorities recommend that practitioners should self-regulate their profession.

#### 5.2.5.4 Final observations

The brief description of the approaches to the practice of non-conventional medicine in the Netherlands, France and the United Kingdom clearly illustrates the disparities in this field in Europe. Each Member State of the European Union has set up its own system, so the practice of non-conventional medicine is a long way from being governed by uniform regulations. This lack of harmony and uniformity, as well as the atypical situation in Belgium, makes it difficult for the Belgian legal framework to draw inspiration from the prevailing situation in the Netherlands, France and the United Kingdom.

# 5.3 TRAINING IN HOMEOPATHY

#### 5.3.1 Introduction

In this chapter, we will describe the different homeopathic schools and their role in the Belgian non-conventional medicine landscape. The three main research questions are:

- how is the training organised?
- is there a quality control on the training?
- is every homeopath able to diagnose and distinguish pathologies?

#### 5.3.2 Methods

The information about the schools is gathered during meetings at the KCE and during contacts by phone. This stakeholder involvement provided the results and some of the ideas presented in the discussion.

#### 5.3.3 Results

# 5.3.3.1 Overview of the schools in Belgium

#### Trainings for persons with a medical training

#### TRAINING IN CLASSIC HOMEOPATHY:

Several homeopathic schools for physicians are gathered in a "Faculty of Homeopathy". All are recognised by the professional union "Unio Homeopathica Belgica" (UHB).

In 1999, Belgian standards for the teaching in homeopathy, were developed, based on the standards of the ECH<sup>109</sup>. These Belgian standards, the Belgian Basic Teaching Program of Homeopathy are used as guidelines in the schools of the Faculty. They define the minimal criteria for training in homeopathy, described in four basic principles:

- I. Admission requirements: only physicians, veterinarians and dentists (including students in their final year of the above described studies) are allowed to obtain the certificate in homeopathy. Pharmacists can follow a specific program, which gives them the opportunity to achieve the necessary knowledge to provide all necessary information and products to the patient. Some schools, such as the 'Vlaamse Studievereniging voor Unitaire homeopatische geneeskunde' VSU, organise specific study groups for each profession in order to provide more specialised courses.
- 2. Goals of the training in homeopathy:
  - Knowledge of the fundamentals of homeopathy
  - Symptomatology and the analysis of the whole of the symptoms
  - Knowledge of the Materia Medica<sup>6</sup> and the therapeutic indications
  - Follow-up of the process after prescription of a homeopathic product
- 3. Organisational structure of the teaching program.:
  - 3 main parts in the training: study of homeopathic theory and adequate repertorisation, study of Materia Medica and the clinical practice (internship)
  - spread over 3 years,
  - at least 200 h of theory and 150 h of clinical practice.
- 4. Importance of postgraduate trainings, including reading scientific literature and attending lectures or conferences.

These schools are open for all physicians, paramedics are allowed to follow the courses but cannot obtain the degree in homeopathy. They offer a basic training of 3 years and deliver a certificate.

Homeopaths can complete this basic training with 2 years of additional training and internship (minimum of 150h) to obtain the national certificate in homeopathy, given by the Faculty. To achieve this certificate, the candidate will have to present two patient cases to a national jury. This Faculty system is based on the same organisational structure in the UK<sup>111</sup>.

The list of schools gathered in the Faculty of Homeopathy are:

- Centre Bruxellois d'Homéopathie Uniciste (CBHU) in Brussels (http://www.cbhu.be/enseignement.html)
- Centre Liégois d'Homéopathie (CLH) in Liège (<a href="http://www.clh-homeo.be">http://www.clh-homeo.be</a>)
- This school offers an intensive course as introduction in classical homeopathy. This course or another basic training at another school have to

Materia Medica are encyclopedia of materials which may be used to prepare homeopathic medicines. They list the materials along with details of the provings which establish the symptoms and conditions for which they seem suitable. They thus constitute a homeopathic prescribing reference guide and are often used along with the homeopathic repertory. 110

be followed before the complete basic training in classical homeopathy can be started. After this basic training, a complementary training is also offered.

- Vlaamse Studievereniging voor Unitaire homeopatische geneeskunde (VSU) in Ostend (http://users.skynet.be/VSU/opleiding vsu.htm)
- Besides the organisation of a training in homeopathy, VSU aims also to inform the general public (in journals and lectures).
- Internationale School voor Klassieke Homeopathie/Clinical training center for Classcial Homeopathy (ISKH) in Hechtel (<a href="http://www.geukens.net/">http://www.geukens.net/</a>)
- In this health care centre the clinical practice is combined with the theoretical study of homeopathy. The students, with a medical preliminary training, can obtain the diploma of classical homeopath after 3 years of full-time training. The part-time training (3 years) is also accessible for non-physicians but a basic medical knowledge is required.
- Ecole Belge d'Homéopathie (EBH) in Tervuren (<a href="http://ebh.homeobel.org/">http://ebh.homeobel.org/</a>)
- The training in homeopathy can also be followed as an e-course.
   The school publishes also a journal on homeopathy (Revue Belge d'Homéopathie) and organises lectures for the general public.
- Wetenschappelijke Vereniging voor Therapiestudie (WVTS) (http://www.wvtsvzw.be/)

The most common organisational structure is in accordance with the above described Belgian standards for teaching in homeopathy (3 years of basic training and 2 years with complementary training and internships). Exceptions on this structure are the schools, which only provide post-graduate training in specific topics of homeopathy (like WVTS) and the full-time basic training at the ISKH.

The other schools (CLH, VSU, CBHU and EBH) offer the combination of the basic training in homeopathy and the postgraduate training.

#### TRAINING IN CLINICAL HOMEOPATHY

The training in clinical homeopathy is offered by the Centre for Education and Development of Clinical Homeopathy (CEDH), its Belgian subdepartment is Alterrmedica (http://www.altermedica.be)

The training consists of a introductory course and the actual training in clinical homeopathic therapy (2 years in 6 weekends, 150-200h). After this training a complementary courses are also offered.

#### Trainings for persons without medical training

The professional union LHC has developed a document containing the criteria for training and the program of the training in homeopathy. This document is based on the guidelines from the European council for Classical Homeopathy and the LHC recognises a list of schools that follow these standards.

The training should consist of a philosophical, a theoretical and a clinical part and is spread over 5 years (during weekends). The philosophical part aims to describe the holistic aspect of homeopathy, which encompasses a different approach and emphasises the study of the fundamental publications of the founders of homeopathy (Hahnemann, Kent).

This training in classical homeopathy is open for everybody, a preliminary training is not required. Persons with a preliminary training are exempt from the medical courses in the first two years, but have to participate at the final medical exam in the third year. These medical courses count for 33 study points on the total of 180 study points for the entire training in homeopathy.

An overview of the courses in homeopathy are given in the next table.

Table 1: overview of the courses in homeopathy for non physicians 112

Year	Medical courses	Homeopathic theory	Clinical Practice	Complementary courses	Certificate
Pathology	the founders				
	(organon of the				
	Healing Art <sup>7</sup>				
	trends in				
	homeopathy				
	Materia Medica				
2	Idem	idem			Basic
					homeopathy
3	Emergency	Materia Medica	Clinical	Psychology	Trainee in
	medicine	Methodology	practice	Management	homeopathy
	Pharmacology	of the			
	Diagnostic	homeopathic			
		analysis			
4		Typology in	Video	Psychology	
		homeopathy	Life cases	Management	
		Materia Medica		Ethics	
5			Internship	final exam	Classical
				defence of a thesis	homeopath

LHC recognises following schools in Belgium:

- Wetenschappelijke vereniging voor Therapiestudie (WVTS),
- Centrum voor Klassieke Homeopathie (CKH),
- Ecole Belge d'Homéopathie,
- International School for Classical homeopathy (ISKH),
- Vlaamse Studievereniging voor Unitaire Homeopathische geneeskunde (VSU).

Several schools in the Netherlands are also recognised.

# 5.3.3.2 Quality control

None of the schools collaborates with an university or college.

In order to guarantee the quality of education, guidelines are developed by the European Homeopathic organisations and these guidelines are modified to the Belgian situation by the professional unions or by the Faculty (see description above).

#### 5.3.3.3 Exclusion diagnosis

In this report, we define the a medical diagnosis as the recognition of symptoms, the defining of a pathology, the recognition of risk factors and the differential diagnosis with other pathologies.

This competence is considered as a necessary tool in primary care and belongs to medical knowledge of a physician. In order to rectify the lack of this knowledge, schools for non-physicians have incorporated medical courses in their program. Question is of an approximately 127h are enough to become equivalent to a physician?

Organon of the Healing Art: (Organon der rationellen Heilkunde) by Samuel Hanhemann, 1810, laid the foundations of all theory and method of homeopathy. The work was repeatedly revised by Hahnemann and published in six editions, with the name changed from the second onwards to Organon of Medicine (Organon der Heilkunst).<sup>113</sup>

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#### 5.3.4 Discussion

The historical development of homeopathy in Belgium has lead to the establishment of a coordinating body, the Faculty in Classical Homeopathic Medicine, gathering the different schools in Belgium. The role of this faculty is to impose quality guidelines for the teaching program and to promote the classical aspect of homeopathy. This could lead to an uniform vision on classical homeopathy. The faculty can be interpreted as a defence against the growing interest in clinical homeopathy.

Both physicians-homeopath and non-physicians homeopaths share the same ("classical"/"unicist") vision on homeopathy. The divergence between both trainings is the medical preliminary training. Basic medical courses are included in the training for non-physicians, but the training emphasizes the homeopathic approach. We did not find enough elements to assure that these courses are sufficient to develop the competence of posing a medical diagnosis and to be aware of the existing conventional therapies.

#### 5.3.5 Conclusion

Physicians can choose between a training in classical homeopathy or in clinical homeopathy. Several schools offer training in classical homeopathy, while only one organisation organises a training in clinical homeopathy.

In contrast to the physicians, non-physicians can only choose for the training in classical homeopathy. Basic medical courses are included in this training, but due to the lack of a control system, no conclusions can be made about the quality of these courses and the ability of these homeopaths to work as primary health care provider.

#### Key messages

- The medical preliminary training determines the accessibility to the different schools in homeopathy
- The trainings in classical homeopathy for physicians are gathered in the Faculty of Classical Homeopathic Medicine
- Next to classical homeopathy is training in clinical homeopathy offered by Altermedica. This training is only accessible for physicians
- For non-physicians a training in classical homeopathy is organised at the CKH
- Both professional unions (LHC and UHB) developed teaching standards.

  These standards are the minimal criteria for teaching in homeopathy and are the guidance for recognition of the training of a new member
- The average training in homeopathy for physicians last 3 years for the basic training and a complementary 2 years of training and internship to obtain the national certificate in classical homeopathy, recognised by the Faculty
- The average training in homeopathy for non-physicians last 5 years
- . In Belgium no quality control system exists for the training in homeopathy

# 5.4 PROFESSIONAL ORGANISATIONS

# 5.4.1 Objectives

The aim of this chapter is to describe the recognised professional unions in Belgium.

Research questions are:

- How are the professional unions organised (description of the professional unions)?
- What is the point of view of each professional union concerning the profession and the role of research in homeopathy?

#### 5.4.2 Methods

The information about the reimbursement policy is gathered during meetings at the KCE and contact by phone. This stakeholder involvement provided the results and some of the ideas presented in the discussion.

#### 5.4.3 Results

# 5.4.3.1 Description of the professional unions

The most recent Royal Decree (6<sup>th</sup> of April 2010) recognises two professional unions of homeopaths: Unio Homoeopathica Belgica (UHB) and Liga Homeopathica Classica (LHC).

The table in appendix summarizes the main characteristics of the professional unions. More information about the historical background of both professional unions can be found in the chapter on the history of homeopathy worldwide and in Belgium.

Unio Homoeopathica Belgica (UHB) is founded in 1987 and has 314 members.

All members have a basic training in medicine, dentistry, veterinary medicine or in pharmaceutics and have obtained a certificate of homeopathy at one of the schools, gathered under the Faculty (more information about this Faculty can be found in the chapter on trainings in homeopathy). Other criteria for membership are attending postgraduate courses and the subscription to a professional liability insurance. The professional union consists of effective members (all practicing homeopaths with a medical certificate), honorary members and affiliated members, including the pharmacists.

#### Missions of UHB are:

- Protection of the professional interests of the members
- Legal protection of the members in case of charge against the professional activity of a member
- Protection of the homeopathic practice
- Contacts and collaboration with the European Committee for Homeopathy (ECH) and the Liga Medicorum Homeopathica Internationalis (LMHI)
- Promote and support the quality of homeopathic science
- Press charges against all unions that promote the homeopathic practice by therapists without medical preliminary training

More information about this professional union, can be found on the website: <a href="http://www.homeopathy.be/">http://www.homeopathy.be/</a>

Liga Homeopathica Classica (LHC) is founded in 1999 and counts 40 members.

LHC gathers all homeopaths, physicians and non-physicians, who practice homeopathy on the classical manner, as described by the founder Hahnemann. Homeopaths who practice homeopathy but not on the classical manner, for example using treatments with complex products, are denied membership. Recently the registration procedure has become more rigorous in order to exclude all members without a certificate in homeopathy delivered by CKH (Centrum voor Klassieke Homeopathie) or equivalent training according to the standards of the ECCH. More information about these standards are given in the chapter on training.

The members get financial incentives to attend postgraduate courses.

# Missions of LHC are:

- Protection of the professional interests of the classical homeopaths
- Establish standards that guarantee the level of competence of the members
- Participate in scientific research
- Establish deontological standards concerning the patient-therapist relationship and between members

 Legal protection of the members in case of charges against the professional activity of a member

The LHC is member of European Council for Classical Homeopathy (ECCH) and International Council of Homeopathy (ICH).

More information about this professional union, can be found on the website: <a href="http://www.ligahomeopatica.be/">http://www.ligahomeopatica.be/</a>.

# 5.4.3.2 Point of view of the professional unions

In this study we focused on the homeopaths who are member of a professional union in homeopathy. Information about the other homeopaths is only derived from stakeholder involvement meetings and could not be validated. We tried to represent the different points of views as objective as possible, but this text must be seen as a mixture of results and discussion.

#### **Profession**

The homeopathic scene in Belgium is divided in two parties, on one side the physician-homeopaths (UHB) who claim homeopathy as a medical practice and on the other side the non-physician-homeopaths (LHC) who consider homeopathy as a therapy with his own philosophy and approach without the need for a medical preliminary training. Between both groups of homeopaths some sharp divisions were noted concerning the role of homeopathy in medicine, but of the conversations with the representatives of these professional unions revealed also some common visions (see later).

The discussions between both professional unions can be reduced to two main questions: is homeopathy a complementary or an alternative medicine and is a medical background necessary to act as a homeopath (see later)?

Is homeopathy a complementary of an alternative medicine?

The UHB-members claim that homeopathy is complementary to the medical practice, in which a medical diagnosis is made and a clinical examination (could be together with technical examinations) has been done. Homeopathy is seen as a tool to enrich the medical diagnosis and to embed complaints in the whole patient (holistic view on the patient). The homeopathic products are prescribed as monotherapy or complementary to the conventional medicines, in order to reduce the amount of conventional medicines or to decrease the possible side-effects of these medicines. For this point of view on homeopathy, a medical certificate is necessary in Belgium. Only physicians have the legal ability to pose a diagnosis and to prescribe medical products.

On the other hand can homeopathy be seen as an alternative medicine. This point of view is most shared by the members of the LHC. Homeopathy has its own philosophy and approach of the complaints of the patient. More details about this philosophy and approach can be found in the chapter on the historical background and in the introduction of this report. In general can be stated that both physicians and non-physicians set up the goals of treatment based on a medical diagnoses (posed by the physician-homeopath himself or by another physician), but the determinant role of homeopathy differs between both therapists. Whereas the physician-homeopath will include homeopathy as one of the therapy modalities in his treatment, will the non-physician homeopath see homeopathy as a treatment on itself.

The lack of compromise between these two visions has led to the request of the UHB to set up two separate chambers for homeopaths instead of one chamber or to be the only representative of the homeopaths in the chamber of homeopathy, as defined in the law Colla (more information about this law can be found in the chapter on the legal aspects). For the UHB it's unacceptable that the LHC is considered as one of the professional organisations, representing the homeopathic community in Belgium and for the UHB it's unacceptable to discuss about the future of homeopathy in Belgium with non medical qualified practitioners in the same chamber.

# Is a medical background necessary to handle as a homeopath?

The complementary or alternative aspect of homeopathy already mentions the role of conventional medicine in the homeopathic practice. The physicians claim the practice of homeopathy only by physicians, whereas the non-physicians consider homeopathy as a medicine on its own with its own approach. A similar discussion can be found between the professional unions in acupuncture (see previous report on acupuncture<sup>114</sup>) with the difference that all acupuncturists had at least a paramedical training. In this case the training in homeopathy for non-physicians even does not require a preliminary training in paramedics (see the chapter on trainings in homeopathy). This leads to a situation where homeopaths without any (or a very concise) medical knowledge treat patients and consider themselves as able-bodied members of the medical staff.

In order to support their position, physician homeopaths quote the advice of the Royal Academy of Medical Science (French section) stating that homeopathy must stay in medicine:

« Il n'en reste pas moins vrai que la popularité du recours aux médecines alternatives, en particulier à l'homéopathie, est un fait réel qui démontre que ces pratiques répondent à une demande sociale forte qu'il convient de respecter. Dans ce cadre, il est effectivement important, pour la sécurité des patients que cette pratique soit réservée à des médecins d'autant qu'il apparaît que les profils de comportement des médecins généralistes pratiquant, en Belgique, l'homéopathie ne divergent pas de ceux des praticiens de la médecine générale conventionnelle en termes de demande d'examens (imagerie et biologie) ni de choix thérapeutiques pour les diagnostics classiques de la médecine conventionnelle, si ce n'est une prescription moindre d'antibiotiques et d'anti-inflammatoires. Pratiquée dans ce contexte, l'homéopathie ne présente pas de risque en terme de santé publique, ... »<sup>13</sup>

The vision on the homeopathy itself is more similar amongst both professional unions: both claim the classical approach of homeopathy with the use of unitarian products. The principle of Unitarian products is based on the philosophy of the founder, Hahnemann. Goal of the homeopathic treatment is to find out the specific product which correspond to the specific type of patient. In contrast to complex products with a mixture of several products, where it is more difficult to find out which product was most effective. More information about this principle is explained in the introduction of this report.

The UHB represents the physicians-homeopaths, but they are also aware that only a minority of the physician-homeopaths are member of the professional unions. They estimate that about 3000 physicians in Belgium prescribe homeopathy whereas only 300 physicians are member. Main difference between both groups of physicians-homeopaths is the determinant role of homeopath in the clinical practice of the physician. Whereas the majority of the members of the UHB are full-time homeopaths, only a minority would be a full-time homeopath in the group of the non-members. These physicians would prescribe homeopathy occasionally or in specialised cases. Also the quality of the training in homeopathy can vary from a one day session to a full training course.

Both professional unions share a common expectation, the integration of homeopathy in the conventional medicine and the recognition of the training in homeopathy at recognised homeopathic schools. Difference between both unions is that the physicians consider homeopathy as a medical practice, part of the integrative conventional medicine, whereas the non-physicians see their role next to the physician or even instead of the physician as an alternative medicine. The UHB's other requests for the future of are: the integration of the training in homeopathy in the training of the general practitioner, the recognition of homeopaths as supervisor of practical trainings at the university, the recognition of the education of the homeopathic-physician at recognised homeopathic schools (similar as sports medicines) and more research about the cost-reducing effects of homeopathy in comparison with conventional general practitioners.

#### Research

The studies mentioned below are performed by the UHB. No studies or research projects performed by the LHC could be found.

In 2002 a study looked at the number of prescriptions of medical imaging and of clinical biology tests by physician-homeopaths in comparison with general practitioners. There were no indications for strong differences in the profile of prescription of medical analyses between homeopaths and general practitioners nor in the number of prescriptions or in the total cost but there was a difference in the number of analyses per prescription. However, interpretation of these results are hampered due to the small sample size and the large variability between the practitioners.

In 2006 a pilot-study on allergic rhinitis has been performed as preparation for a RCT with logistical support by the UHB <sup>115</sup>.

In 2008 the UHB has organised the "World conference on homeopathy" in Ostend (Belgium).

In 2010, a booklet on the scientific framework of homeopathy was published by Dr. Michel Van Wassenhoven, in collaboration with LMHI and ECH. In this publication several topics are discussed, like the ethical aspects of non-conventional medicines, the clinical homeopathic practice in Belgium and the literature review of efficacy, effectiveness, quality of life and cost-effectiveness. The information in this booklet was used in this report for background information. The research methods are not always clearly mentioned, which hampered the interpretation of the results.

The professional union also aims to improve the accessibility to homeopathic products in after-hours services. A book is published that describes 100 products in 10 steps are described for the healing of the patient in acute situations. These 100 products are also available in a kit. This kit is available in each pharmacy on duty.

The UHB participated at studies about the consumer profile in 1999 (an observational study of patients receiving homeopathic treatment", a six countries survey) and in March 2011 (new observational study is right now going on in six European countries and in Brazil).

Members of the UHB participated in several proving of new or already known substances: Insulinum (2005); Lobelia cardinalis (2006); Galium aparine (2007) and Eriodictyon californicum (2009).

According to the homeopaths, the pharmaceutical industry is also a determining factor in the development of the profession in Belgium due to the fact that homeopathy is not only a provision of services but implies also the prescription of homeopathic products.

#### 5.4.4 Conclusion

Both professional unions share the same, classical vision on homeopathy, but strongly disagree on the need for medical knowledge of the homeopath in clinical practice. The UHB consider homeopathy as one of the medical therapy modalities of the physician, based on a medical diagnosis and clinical examination, whereas the LHC consider homeopathy as a medicine on its own, in which the medical diagnosis only plays a role in determining risk factors of serious pathologies.

#### Key messages

- Unio Homeopathica Belgica (UHB) represents the physician-homeopaths, whereas the Liga Homeopathica Classica (LHC) represents all classical homeopaths (with and without a medical certificate)
- Professional unions disagree on the necessity of a medical knowledge to practice homeopathy
- Both professional unions share the same vision on homeopathy: the Unitarian of classical homeopathy, based on the principles of the founder, Hahnemann.

The UHB supports several research projects concerning homeopathy and its use in Belgium.

# 5.5 PATIENTS' ASSOCIATION

# 5.5.1 Objectives

This chapter describes the patients' associations in Belgium.

#### 5.5.2 Methods

The information about the patients' association is gathered during a meeting at the KCE and through contacts by phone.

#### 5.5.3 Results

There is one patients' association in Belgium, Pro Homeopathica (former name "De Vrienden van de Homeopathie/Les amis de l'Homéopathie) (http://www.amivrihomeo.be/index.php).

It was founded in 1972 and aims to inform his members and the general public about the value of homeopathy, by organising lectures and publicising a bulletin (four issues per year).

Nowadays a changeover in the board has lead to a decreased activity but still between 500 and 700 patients are member of this association. No accurate data about the number of members was available.

Some concerns about the accessibility to homeopathy were suggested by the representative of the association:

- the demographic spread of the homeopaths: the mean average of the homeopaths, member of UHB, is 54 years (study performed by UHB) and there is a tendency noticed in a decreasing number of young physicians who are willing to study homeopathy.
- the offer of homeopathic products: this is restricted to the list of products reimbursed by the complementary insurance, established by the sickness funds and by the offer of the pharmaceutical companies. In some cases the patients experiences some difficulties to obtain the homeopathic product he needs.

The patients' association is member of the European Federation of Homeopathic Patients' Association (EFHPA)<sup>116</sup>.

#### 5.5.4 Conclusion

The patients' organisations, Pro Homeopathica, represents the vision of the patients on homeopathy. Main goal of this association is to inform the general public about homeopathy.

#### **Key Messages**

- One patients' organisation, Pro Homeopathica, gathers patients who are satisfied of their homeopathic treatment
- Pro Homeopathica aims to inform the general public about homeopathy

# 5.6 REIMBURSEMENT POLICY CONCERNING HOMEOPATHY

#### 5.6.1 Introduction

This chapter aims to describe reimbursement policies of sickness funds for homeopathy.

#### 5.6.2 Methods

The information about the reimbursement policy is gathered during meetings at the KCE and contacts by phone. The results and the ideas for discussion came out of this stakeholder involvement. We limited ourselves to the reimbursement policies of the 5 biggest sickness funds in Belgium.

#### 5.6.3 Results

#### 5.6.3.1 Reimbursement policy for ambulatory treatments

The four non-conventional medicines (osteopathy, chiropractic, acupuncture and homeopathy) are not covered by the compulsory health insurance. Most of the sickness funds provide a partial reimbursement of these non-conventional medicines under the coverage of the complementary health insurance. All sickness funds have a national department, the national alliance, which can set up the criteria for reimbursement. Still, the local departments are also free the set up their own criteria, resulting in local differences in criteria within a sickness fund.

This partial reimbursement is restricted to an average of 10 Euros per session, with a ceiling for the number of sessions per calendar year (maximum 5 sessions of non-conventional medicine per calendar year). These 5 sessions comprise the four non-conventional medicines. For example: the reimbursement of 5 sessions non-conventional medicines can be used for 3 acupuncture sessions and 2 treatments by an osteopath. The representatives of the sickness funds mentioned the increase of reimbursements of non-conventional medicines, in particular an increased number of patients who consult an non-conventional therapist and an increased number of non-conventional therapists (particularly osteopathy and homeopathy).

In addition to reimbursement by the sickness funds, patients can also claim reimbursement through outpatient costs insurance. These policies cover up to 80% of outpatient medical costs, including the non-conventional medicines. Such services must have been prescribed by a doctor. Only consultations done by qualified practitioners are reimbursed.

# 5.6.3.2 Reimbursement policy for hospital-related treatments

Some insurance companies reimburse 40 to 50% of the fees under the coverage of a hospitalisation insurance. Main criteria are: a direct link with the raison for hospitalisation, the treatments have to be performed under medical prescription and by qualified therapists.

# 5.6.3.3 Specificities for homeopathy

## Reimbursement for homeopathic products

A first agreement between the sickness funds, restricted the reimbursement of homeopathy to the partial reimbursement of homeopathic products. The list of homeopathic products <sup>117</sup> is established after consensus with the only professional union at that moment, i.e Unio Homeopathica Belgica. To ensure the safety of the products for the patients, all products have to be diluted with 10000 (D4), they may not be derived from human or animals' organs and may only be applied orally. These products have to be prescribed by a physician (whether or not homeopath) and have to be delivered by a pharmacist. In the software system of the pharmacist all recognised homeopathic products are characterised with an asterisk and the pharmacist delivers an uniform certificate (BVAC-certificate) (BVAC-Bijkomende Verzekering Assurance Complémentaire). With this certificate the patient can request a partial reimbursement of homeopathic products, but also for other products such as vaccines, contraceptives and smoking cessation medication. The partial reimbursement ranges from 20 to 50% with an average ceiling of 70euros per year (ranging from 62 to 186euros per year). The Christian sickness fund is the only sickness fund with no ceiling for reimbursement.

Some private insurance companies provide a reimbursement up to 80% for homeopathic products after ambulatory consultation and between 40 and 50% for homeopathic products, related to a recent hospital stay.

#### Reimbursement for homeopathic consultations

Nowadays, some sickness funds, like the Independent sickness funds and the Neutral sickness funds, reimburse also the consultation with a homeopath. This reimbursement is restricted to consultations by a physician and is also restricted in amount and number of sessions (10 euros per consultation with a ceiling of 5 sessions of all non-conventional medicines per year). In contrast to the recognition of the therapists of the other non-conventional medicines, no additional criteria, next to the medical degree, are set up for the homeopaths. These physicians are allowed to double reimburse their consultation, partly by the compulsory health insurance for the 'medical consultation' itself, and partly by the complementary health insurance for the non-conventional therapy.

The sickness funds do not provide any reimbursement for homeopathic products or for the homeopathic consultation, provided by a non-physician-homeopath.

An overview of the results is given in the appendix.

#### 5.6.4 Discussion

In the 10 years-period between the first announcement of the law Colla and the execution of this law, the sickness funds regulate their own system of reimbursement of the non-conventional medicines. This regulation went together with the auto-regulation of the professional unions and schools in these medicines.

In general the reimbursement of non-conventional medicines is restricted to the reimbursement of the provision of services. For homeopathy a particular reimbursement system was set up, by determining a list of recognised homeopathic products. The patient is more guided in the overwhelming offer of homeopathic products and the safety of patient is more guaranteed by the supervision of the physician.

Some sickness funds provide also reimbursement for the consultations by a homeopath. The reimbursement is restricted in amount and number of sessions and is only for the physician-homeopaths. But this system of reimbursement is in favour of the physicians. Whereas the non-physician-homeopaths are not recognised by the sickness funds and are not allowed to prescribe homeopathic products, has the physician-homeopath the freedom to double count a same treatment session as a conventional therapy (reimbursed by the compulsory health insurance) and a non-conventional therapy (reimbursed by the complementary health insurance).

This freedom results in a double reimbursement for the patient and will advantage the physician-homeopaths in comparison to the non-physician-homeopaths.

The sickness funds which provide this system of reimbursement for the homeopathic consultation do not have an active control system to prevent this kind of double counting of the same consultation. In contrast to the osteopaths and acupuncturists, who have to declare only to count one consultation per patient per day.

A final point can be made about the dubious role of the sickness funds concerning the reimbursement of medicines, which are until now not yet fully recognised by the law. The reimbursement is a marketing product on request of the patients and therapists in order to compete with the other sickness funds, but this point of view opened the possible reimbursement of all kind of unrecognised therapies. Nowadays the use of nonconventional medicines is still increasing, leading to a higher expenditure for the sickness funds. And this growing expenditure is used by the proponents to quickly regulate these non-conventional medicines, although the reimbursement of these medicines is made on their own initiative. The growing expenditure in the complementary sickness insurance can also be seen as the result of the long period between the set up of the law Colla and the final execution of this law.

#### 5.6.5 Conclusion

The reimbursement of homeopathy is in general restricted to the partial reimbursement of a list of homeopathic products. Only physicians are considered as recognised therapists by the sickness fund for the prescription of a homeopathic product or for the reimbursement of the consultation. The patient who are treated by a non-physician-homeopath cannot request a reimbursement for the homeopathic products or for the consultation.

The existing system of partial reimbursement is a first step in the quality control of the homeopathic products, but is not elaborated enough to guarantee the safety and the quality of homeopathic products.

# Key messages

- The (partial) reimbursement of homeopathy is provided within the complementary health insurance.
- The consultation by a physician-homeopaths is only reimbursed by the Neutral and the Independent Sickness Fund.
- All sickness funds provide a partial reimbursement of a consensus list of homeopathic products under condition that the product has to be prescribed by a physician and delivered by a pharmacist.
- The amount of reimbursement varies slightly between the sickness funds.

# 6 OVERVIEW AND DISCUSSION

# 6.1 BACKGROUND

The Belgian Minister for Public Health and Social Affairs has asked the Federal Healthcare Knowledge Centre (KCE) to describe the current situation of these practices in order to review or implement the law of 1999 (the so-called 'Colla law').

Acupuncture, chiropractic, osteopathy and homeopathy can be classified under the label of complementary and alternative medicines (CAM). In 2007 the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institute of Health (US) defined these medicines as a 'group of diverse medical and healthcare systems, practices and products that are not currently considered to be part of conventional medicine'<sup>118</sup>. These therapies are referred to as 'complementary' where they are used jointly with conventional treatments, and as 'alternative' where they are used instead of conventional treatment.

These medical practices differ from classic medicine in the sense that they are not based on empirical science. Nonetheless, many patients resort to these.

This report is the last in a series of three: after osteopathy, chiropractic and acupuncture, we now analyse homeopathy, focusing on homeopathy practices and practitioners. Indeed, this report does not address the specific issue of homeopathic remedies.

Homeopathy is a therapeutic method developed more than 200 years ago by German physician and scholar, Dr Samuel Hahnemann. It relies on the administration of preparations made from highly diluted and dynamised mother substances. This 'medicine' is also based on certain principles, established as proper laws, including the famous law of similars, ascribed to Hippocrates, which states that agents that cause symptoms in a healthy person will cure the same symptoms in a sick person. Every homeopathic remedy of animal, plant or mineral origin relates to the symptoms that a healthy person would manifest if they absorbed this substance. Associated with this first principle is a specific technique for preparing homeopathic remedies, based on the principles of high dilutions and dynamisation (or potentisation), which are believed to release the inner, spirit-like essence of substances, with the ability to act on patients' vital force. In addition to the law of similars, and the principles of dilution and dynamisation of remedies there is the law of individualisation of treatment (there are no diseases, but only patients), used in conjunction with the concept of the patient's 'terrain'. These four principles are the foundation of classical homeopathy, which has since diversified greatly.

In Belgium, it has been practised by physicians for nearly 200 years and, more recently, by non-physicians too.

# 6.1.1 Objectives and methods

The report aims to respond to the following questions:

- 1. How effective is homeopathy? What are the benefits and harmful effects?
- 2. How can homeopathy be defined, and how is it used by the Belgian population?
- 3. What is the legal status of these medicines and how are they organised in Belgium?
- 4. How are the therapists trained?

In order to grasp these medicines in their complex and multidimensional nature, a range of methods were used:

- the medical literature was analysed to assess the clinical effectiveness and safety of the therapies under study;
- a telephone survey of the general population gave a view on the scale of the consumption of these therapies (n=2000);

- a socio-anthropological interview-based survey gauged the perceptions of regular users (n=9) and therapists (n=10);
- an online survey among practitioners describe their characteristics and those of their practices (n=144/330);
- a detailed analysis of the legal and organisational framework helped to understand the Colla law, the hold-ups and issues;
- consultation with the professional associations and experts gave an insight in how these professions are organised and how their practitioners are trained.

Together they draw a picture of the current state in Belgium but they cannot provide a complete answer to the initial research questions because of the limitations of each method and the resulting limitations of the material collected.

The results of our several sub-studies were pooled, to end up with a more representative, multidimensional overview of the homeopathy practice in Belgium today, anno 2011.

#### 6.2 LIMITATIONS

In spite of the range of methods used, this study has come up against a number of limitations, the most important of which are described below.

- The literature search was confined to a review of reviews, that is to say, it excludes the findings of the latest primary studies. The quality of the reviews was variable but generally acceptable. However, many of the studies included in the reviews were of poor quality. Given the emphasis placed on systematic reviews, the review of literature is biased in favour of subjects or studies for which a systematic review has been published.
- The sociological aspect is exploratory and the user survey focuses on a small and purposive sample of regular users likely to be convinced of the worth of the therapy and who are therefore not representative of the entire user group and still less of the entire population. However, the findings have thrown more light on the results of the survey of the general population and provided information on the perception of homeopathy and on the way in which consultations are conducted.
- Similarly, therapists who agreed to an interview may not be representative of all therapists.
- The Internet survey of practitioners is representative only of homeopaths
  who are affiliated with a professional association, although membership is not
  a prerequisite for practice. We have no information on the exact number of
  practitioners practising homeopathy or using it occasionally. In fact, according
  to professional associations, only 10% of homeopathic practitioners are
  affiliated.
- We were unable to study further the position of homeopaths on vaccination because the professional associations and schools that were asked to adapt the questionnaire did not accept the question.
- The telephone survey involved adults. There was no question targeted specifically at children.

Lastly, our methodology does not capture the full use of homeopathic products, such as self-medication, products purchased directly from pharmacies on the advice of a pharmacist or products prescribed by general practitioners or paediatricians who do not practise or are not trained in homeopathy.

# 6.3 HOMEOPATHY IN BELGIUM: USERS, PRACTITIONERS AND PRACTICES

# 6.3.1 Increasing use of non-conventional forms of medicine

The national survey on individuals' health care behaviour and consumption, conducted by the Belgian Scientific Institute of Public Health ((WIV-ISP) every four years, had already highlighted the success with the general public of alternative (or non-conventional) forms of medicine. In 2001, 11% of respondents had consulted an 'alternative therapist' in the past 12 months, and 12% in 2008. More particularly, 6% of the sample group had consulted a homeopath in 2001 and 2004, and 4% in 2008<sup>119</sup>.

According to a KCE study conducted in 2009 among a representative sample of Belgian adults, one-third of respondents had already consulted an alternative therapist at least once in their lifetime and, during the past 12 months, 7% had consulted an osteopath, 6% a homeopath, 3% an acupuncturist and 2% a chiropractor. This is quite a significant number.

#### 6.3.2 Who are the patients?

The general patient base of homeopaths covers all stages of life. Some homeopaths seem to be more specialised in a female patient base (46%), while nearly half have a mixed patient base (49%).

According to the patients interviewed, they use the services of homeopaths for back problems (31%), neck pain (14%), allergies (11%) and fatigue (9%). The perception of therapists differs slightly in this respect, as they say their services are used mainly for ailments of the upper respiratory tract (in general) and problems of depression and anxiety.

On the whole, homeopaths are required to treat patients for general indications that might have prompted them to consult a conventional general practitioner instead.

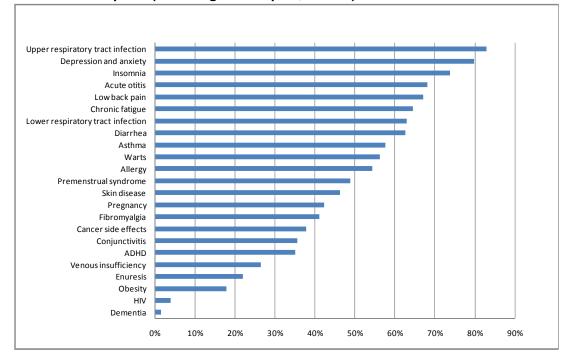


Figure 1: Frequent and very frequent causes for complaint encountered by homeopaths (according to therapists, n = 144)

Besides the type of indications for which a homeopath is consulted, regular patients say they are seeking an alternative type of medicine that is more natural, less aggressive and more customised.

## 6.3.3 Who are the practitioners?

In Belgium, there are currently around 340 practising homeopaths who are affiliated with a professional association. Nearly half are aged between 40 and 59 and a little over a quarter are women (28%). In 75% of cases, their initial training is in medicine and 3.5% are nursing graduates. Nearly one-fifth of affiliated homeopaths have no (para)medical training.

However, as we have already mentioned, we have no information on the exact number of practitioners or occasional users of homeopathy. In fact, according to professional associations, affiliated homeopaths represent only 10% of practitioners and they are mainly 'unicists' (practising classical homeopathy), which seems to be a minority trend in the profession at present.

In Flanders, more homeopaths are affiliated with one of the two professional associations than in Wallonia or Brussels.

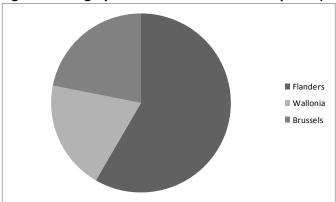


Figure 2: Geographical distribution of homeopaths (n = 139)

The majority of affiliated homeopaths work alone (78%) and, when they are in group practice, they work chiefly alongside physicians or homeopaths.

On average they have practised homeopathy for 17 years and combine it with general practice (71%) and/or acupuncture (24%), with half devoting 80% of their time to homeopathy.

Therapists use a variety of homeopathic approaches: 'classicist—unicist' homeopaths are loyal to Hahnemann's teachings and seek a single remedy tailored to each individual patient. They represent the great majority of homeopaths affiliated with a professional association (75%). 'Complex—pluralist' homeopaths (13% of the homeopaths interviewed) prescribe a combination of 'contextual' and 'fundamental' remedies. Finally, clinical homeopaths (20% of our sample group) favour the use of homeopathic remedies designed to act on a specific organ or system. These remedies may or may not be delivered in complex form and usually in low dilution.

Belgian homeopaths may join two professional associations: Unio Homeopathica Belgica (UHB), which has just over 300 members (early 2011) including physicians, veterinarians, dentists and pharmacists who have graduated from a school recognised by the 'faculty of homeopathy'. Liga Homeopathica Classica (LHC) has 40 members, all 'classical' physician and non-physician homeopaths (half of whom have no medical training). Both of these professional associations uphold 'classical' homeopathy.

#### 6.3.4 Typical patient route

#### 6.3.4.1 Taking the plunge into alternative medicine

Patients who have already consulted an alternative therapist do not reject conventional medicine but tend to use it as part of a complementary approach. Indeed, the telephone survey of the general population shows that, in general, 87% of respondents using alternative medicine also consult a conventional physician, more often than not for the same medical reason.

However, interviews with regular homeopathy users reveal that they generally favour the homeopathic approach owing to their distrust and criticism of the efficacy, and especially the side effects, of conventional medicine.

This means that they reserve homeopathy for certain indications or diseases and conventional medicine for others, either with the same therapist (physician homeopath) or with different therapists (e.g., physician homeopath and specialist).

When a patient is referred to a homeopathy practitioner it is mainly by word of mouth, on the advice of relatives or acquaintances. A whole host of patients have been treated with homeopathy since childhood and have remained loyal to this therapeutic approach.

Note also that 4% of the people interviewed by telephone have never used alternative medicine because their attending physician advised them against it.

#### 6.3.4.2 Consultations

In 50% of cases, an initial appointment with a homeopath is obtained in seven days.

For a child, the **initial consultation** with the majority of practitioners (51%) lasts between 30 and 60 minutes and for an adult, between 60 and 90 minutes (41%). Among 23% of affiliated homeopaths, it exceeds 90 minutes.

Follow-up consultations are shorter, generally lasting 30 minutes.

An in-depth **anamnesis** (case-taking consultation), relating to matters that may surprise patients, will enable unicist practitioners to identify, or move as close as possible to, the *similimum* (the single most appropriate remedy for the individual) and will enable complex or clinical practitioners to identify several homeopathic remedies.

In the first year, most patients will be seen by an affiliated homeopath four to six times (52%) and between one and three times the following year (66%).

The prescribed **remedy (or remedies)** will be purchased in a pharmacy, although some homeopaths stock them. Some remedies are on a common list compiled by all sickness funds. They may therefore be subject to reimbursement (the annual amount of which is capped), either via the supplementary outpatient insurance or private insurance, and in the latter case also in the context of hospitalisation.

Some remedies are only available to order, which practitioners say can pose a problem in acute cases. This problem can be circumvented by patients keeping basic homeopathic remedies at home or if duty pharmacies were to stock a kit of 100 remedies, as recommended by the UHB.

It has not been possible to evaluate the consumption of homeopathic remedies by the general population for lack of reliable and accessible data.

For **subsequent episodes of illness**, regular users may engage in a form of assisted self-medication, whereby patients take a known remedy after checking with their homeopath whether this is the right choice, or after a telephone consultation. Unless the symptoms improve significantly within two to three days, the patient will be asked to make an appointment.

#### 6.3.5 Financial aspects

A consultation with an affiliated homeopath will cost patients between EUR 50 and 80 (euros) for an initial consultation (49%) for an adult and between EUR 35 and 80 for a child (79%). Follow-up consultations rarely exceed EUR 50.

These fees are higher than for the other three non-conventional medical practices we studied previously.

The compulsory health insurance does not reimburse homeopathy as such. However, patients who have consulted a physician will benefit from reimbursement for a 'conventional' medical consultation via the compulsory health insurance if the physician has completed a treatment form (attestation de soins). This is likely to be the case, as physician homeopaths claim to practice medicine first and foremost.

In addition, some homeopathic remedies from a list common to all sickness funds will be partially reimbursed by the supplementary insurance and, in some sickness funds, the consultation itself will be subject to an additional reimbursement for the use of non-conventional therapies as part of the supplementary insurance (between EUR 10 and EUR 12.5 per consultation for a maximum of five sessions of alternative therapies per year). These measures do not apply to consultations with non-physician homeopaths.

Some private insurance companies also provide for reimbursement. This will depend on the type of coverage purchased.

So the financial cost of using such practices is high and in the main is borne by the patient. Indeed, the telephone survey indicates that 12% of respondents have never used a non-conventional form of medicine because they find it too expensive.

#### 6.3.6 Patient rating

Regular homeopathy users particularly appreciate their therapist listening to their concerns, the time devoted to them, the customisation of treatment, the lack of side effects from the prescribed remedies and the natural approach of this practice. They have also experienced the (subjective) efficacy of the therapeutic remedies, which in some cases they consider to be almost miraculous.

Table 2: Consultations with a homeopath

Organisation of the practice	Solo: 78%
Therapist's initial training	Medicine: 75% Nursing: 3.5% No (para)medical training: 20%
Therapist's other activities	General practice: 71% Acupuncture: 24%
Waiting time for an appointment	New patient: seven days (median time) Existing patient: same day
Duration of the initial consultation	Children: 30–60 minutes (51%) Adults: 60–90 minutes (41%)
Duration of follow-up consultations	Children: 30–60 minutes (53%) Adults: 60–90 minutes (41%) Adults: 30–60 minutes (62%)
Therapeutic approach	Unicist: 75% Complex: 13% Clinical: 20%
Fees	Children: €5-80 Adults: €35-50

Reimbursement from supplementary or private insurance	List of homeopathic remedies common to all sickness funds (capped)  Maximum five sessions per year (all types of alternative medicine combined)
Number of sessions per year	Four to six sessions (52%)

## 6.4 IS THERE EVIDENCE OF EFFICACY?

Like any other therapy, homeopathy aims to treat and/or cure patients. It is therefore perfectly legitimate to examine its efficacy. Scientific literature provides what could be termed an objective response, insofar as it can call upon the proven techniques of evidence-based medicine (evidence is the basic principle used to evaluate modern conventional medicine). Patients themselves may provide another type of response, in this case subjective: patients are the subjects and are able to give a personal opinion of their experience.

# 6.4.1 Scientific literature: no evidence of efficacy

Unlike other non-conventional forms of medicine, where some treatments have been found to provide a response to certain indications, the data available in scientific literature demonstrate no efficacy whatsoever in the case of homeopathy. The following indications have been the subject of published studies of sufficient quality to be included in our body of analysis: insomnia, allergic rhinitis, lower back pain, obstetric indications, chronic fatigue, dementia, asthma, enuresis, depression, anxiety, symptoms arising from cancer or its treatment, hot flushes, headaches in children, attention deficit and hyperactivity syndrome, fibromyalgia, human immunodeficiency virus, chronic venous insufficiency and premenstrual symptoms.

While isolated studies demonstrating the therapeutic efficacy of homeopathy have been brandished, the fact remains that they do not meet the requirements for their conclusions to be considered as 'evidence-based'.

Therefore the clinical effect is indistinguishable from the known and demonstrated placebo effect. Moreover, it has its own uses.

Lastly, homeopaths claim that their approach has public health benefits. They state that they prescribe fewer medicines and, most important, fewer antibiotics, saying that this prescribing behaviour is beneficial for both patient health and sickness insurance finances.

It is impossible to test these hypotheses based on existing data.

#### 6.4.2 Patients' views

We find that, in general, users report they are helped by this type of therapy. They claim to be satisfied with homeopathic therapies in many cases.

For patients, their positive experience of the effects of such care is worth any number of studies. They are convinced of the efficacy of treatments. As we were told, "they do not just *believe*, they observe that it works".

#### 6.4.3 What are the risks?

Homeopaths believe that homeopathic products can lead to a worsening of symptoms. However, literature does not document such side effects any more than it does the beneficial effects.

The risk of a delayed diagnosis was reported anecdotally but cannot be accurately assessed.

Homeopaths are commonly believed to oppose vaccination. However, scientific literature is not unanimous on this point: some authors report fewer vaccinations in the patient base of homeopaths, which could be prompted by patients themselves, while other authors show better immunisation coverage in homeopaths' patient base.

The therapists we met during our interviews do not generally favour vaccination, accusing it of adverse side effects and of acting against nature. They also claim that homeopathy can boost immunity sufficiently, enabling vaccination to be dispensed with altogether. However, they say they do administer vaccination, even though they do not encourage it. As the representatives of professional associations rejected the question on vaccination, we have no quantified data on the subject.

#### 6.5 HOW DOES ONE BECOME A HOMEOPATH?

In 37% of cases, affiliated homeopaths arrived at this therapeutic approach because they had been treated using homeopathy themselves and, in 31% of cases, because a family member or friend had been helped by homeopathy.

So, for some it was a vocation, experienced by them and adopted as from medical school, while for others it was a sort of belated conversion, motivated by a desire to practice a 'different' type of medicine focused more on patients than on their symptoms.

Physicians may receive training in 'classical' (or unicist) homeopathy in a number of schools grouped into a 'faculty of homeopathy'. Each school complies with the 'Belgian standards' defining admission criteria (dentists and veterinarians), learning objectives and course organisation (minimum 200 hours of theory and 150 hours of clinical practice) and emphasises the importance of further training. After three years, candidates obtain a diploma in 'basic' homeopathy and, after five years, a certificate in classical homeopathy issued by the 'faculty'.

Training in 'clinical' homeopathy is provided by a centre and is spread over six weekends in a two-year period. Additional courses are also available.

Non-physicians may train in 'classical' homeopathy during week-ends in a total of five years, including 33/180study points of medical courses.

# 6.6 LEGAL FRAMEWORK

This chapter is common to the three reports on alternative medicines, as most of the issues are common to all non-conventional practices (except the part on homeopathic remedies).

#### 6.6.1 Background

During the 1990s, Europe acted as a catalyst in the development of new Belgian legislation concerning non-conventional medicines — at the initiative of a Belgian member of the European Parliament, P. Lannoye. In April 1994, he submitted a proposal to the European parliament 'Committee on the Environment, Public Health and Consumer Protection' concerning the status of non-conventional medicines. He called for non-conventional medical acts to be covered by national sickness insurance systems, the integration of complementary systems into the European Pharmacopeia, and a research budget for non-conventional medicines. It was not until three years later, on 29 May 1997, that a first resolution was proposed by the European parliament. The main thrust of this proposal was to encourage the Commission to undertake a recognition procedure for non-conventional medicines and to carry out studies of their safety, advisability, field of application and their complementary/alternative character. On 11 June 1999, it fell to the Council of Europe to adopt a resolution that called for the integration of non-conventional medicines at European level and governed access to these medicines for both practitioners and patients.

In response to this resolution, Belgium decided to amend its legislation. According to Article 2 of Royal Decree no. 78<sup>75</sup> performing a diagnosis and establishing the treatment of a physical or mental disorder are reserved for the holders of a medical diploma approved by the competent medical commission. Persons that habitually diagnose or organise treatment as described above, who are not doctors, are in principle guilty of the illegal practice of medicine. Homeopaths that perform these acts habitually and are not doctors are working illegally. Patients have no guarantee regulated by the authorities as to the quality of the care and safety.

On 29 April 1999, the Belgian parliament adopted a new law on the regulation of non-conventional medicines, known as the Colla law (after the name of the Minister for Health at the time, Marcel Colla).

#### 6.6.2 The Colla law

The purpose of the Colla law is to guarantee that each patient receives quality care. This is ensured mainly by a dual registration system. Not only must non-conventional practices be registered (which is only possible if they satisfy certain conditions), but all practitioners must also be individually registered (for which they must also satisfy certain conditions). A key role is given to a joint commission, which must advise on the general conditions that apply to the exercise of all non-conventional practices and the conditions that practitioners of a non-conventional practice must satisfy to be registered individually.

However, since in early January 2011 this joint commission had still not been established, it cannot play its key role and consequently the law cannot be fully executed.

The law stipulates that half of the joint commission members should be proposed by the faculties of medicine, and the other half by practitioners of non-conventional medicines proposed by the chambers (art. 5).

One difficulty that arises is that article 5 does not specify whether practitioner-members of the joint commission must be registered individually. In addition, the law does not define what is meant by a 'practitioner of a non-conventional medicine'. As a result, it is not clear whether the law requires these practitioners to be registered for the composition of the first joint committee.

The law states that no one can exercise a non-conventional practice without being registered (Art. 8 §1). Moreover, the rule is that the professional exercise of a non-conventional practice by a non-doctor is tantamount to the illegal practice of medicine, which is a punishable offence, except for certain treatments that the law allows for certain professionals, such as physiotherapists<sup>75</sup>. If we accept the interpretation that individual registration is necessary to assemble the joint commission for the first time, this raises a problem because it is this very joint commission that must give an opinion on the registration conditions<sup>82,83</sup>.

At the request of two associations representing osteopaths, the Brussels court of first instance ordered the Belgian state on 22 January 2010 to set up the joint commission. The government appealed but the judgement was for immediate execution. The Belgian state must therefore pay a fine of 5 000 euros a month as from June 2010.

The practitioner members of the joint commission must be appointed by the chambers, which must be established, with one chamber per non-conventional medicine referred to in the Colla law. These chambers are also constituted of representatives of the medical faculties and members appointed by recognised professional organisations. The composition of the joint commission requires prior recognition of the different professional associations by Royal Decree. The Royal Decree of 06 April 2010 recognising the professional organisations for non-conventional practices, or practices that may be considered for qualification as a non-conventional practice<sup>84</sup>, confirmed the recognition of 13 professional associations that satisfy the recognition criteria.

For this decree to be properly executed, under the terms of the Colla law it must be approved by the Parliament within sixth month after its publication in the Belgian Official Journal. However, as the decree was published on 12 April 2010, it should have been confirmed by law at the latest on 12 October 2010; yet, the vote in the Chamber and the Senate to approve the draft law only took place in November<sup>120</sup>. This decision therefore arrived too late. It could be argued that the decree cannot be executed and, consequently, that all subsequent stages, such as the appointment of the members of the chambers, cannot follow. A possible solution would be to republish the Royal Decree and, this time, approve it properly within six months of its publication.

Another interpretation is that the legislator can in principle not compel its successors to follow the former's decisions . As a result, a new legislator should be able to ratify the law after this period of six months. But, wouldn't changing the general rule with an individual legal application, prejudice the fact that each citizen has the same constitutional rights for the same application of the law in similar cases? Effectively, by ratifying the individual recognition of the professional associations beyond the period of six months, the legislator has departed from the general rule. The members of the professional association that will be recognised in the future therefore have no legal guarantee as to the delays in which their 'Royal Decree of recognition' would be confirmed by law.

#### 6.6.3 Consequences of partial execution of the Colla law

As long as the Colla law is not fully in effect, the practice of a non-conventional medicine by a non-doctor is tantamount to the illegal practice of medicine. Several non-doctor practitioners of non-conventional practices have already been sentenced for this offence. We note however that jurisprudence tends increasingly towards acquittal, insofar as certain conditions (such as proper training) are satisfied and the Belgian state still fails to execute the Colla law. In addition, certain medical procedures that are also more or less in the realm of alternative therapists can be practiced legally by certain professionals such as physiotherapists.

This failure to execute fully the Colla law has as a consequence that any other law that may have an influence on the therapist-patient relationship does not apply. For example, the provisions of the patients' rights act of 22 August 2002 and the law of 31 March 2010 concerning compensation for damages resulting from healthcare can only be applied to the practitioners of a non-conventional medicine when the Colla law has been fully executed.

Two competing concepts of who can practice healthcare coexist within the European Union. According to the first one, in principle only doctors are authorised to practice medicine. Under the second one, any person who so desires can practice medicine, with the exception of certain acts that can only be performed by doctors.

Belgium falls into the first category because it restricts the practice of medicine to doctors, with the exception of certain treatments such as those provided by non-conventional medicines (once the Colla law will be executed).

#### 6.6.4 Homeopathic medicines

Homeopathic products are considered as medicines and may solely be sold in pharmacies. Except for the magistrals, they must be notified to the Federal Agency for Medicinal and Health Products (FAGG/AFMPS). According to the notification procedure - which is inserted as an intermediary phase awaiting the registration or market authorisation of every homeopathic medicine - information related to the quality, the use, the producer etc. needs to be provided. This does not imply any evaluation of these topics. Before entering the market, homeopathic medicines for oral or external use where no specific therapeutic indication is claimed and where its dilution level is such that the safety of the medicine is guaranteed, have to pass the registration procedure. Quality, safety and the justification for homeopathic use are assessed by the Commission for homeopathic medicines for human and veterinary use. Homeopathic medicines that do not meet the above mentioned criteria need to pass the marketing authorisation procedure where the assessment includes quality, safety and efficacy/homeopathic use in accordance with the principles and specificities of homeopathic medicine.

# 7 IN CONCLUSION, WHAT ARE THE FUTURE IMPLICATIONS?

Our results highlight different implications at different levels: for both therapists and patients at the legislative level; for patients at the safety and information level and for therapists at the level of their role in the health care system.

Note that we have not addressed the 'homeopathic remedy' aspect, and the relevance or manner of considering them as medicines or otherwise, beyond a purely legal perspective.

# 7.1 NO SCIENTIFIC EVIDENCE OF CLINICAL EFFICACY EXISTS

From a purely clinical perspective, the fact remains that there is no valid empirical proof of the efficacy of homeopathy (evidence-based medicine) beyond the placebo effect. In the case of homeopathy, the placebo effect probably has some significance but it is difficult to define.

Therapists base the success of their treatments on their subjective experience and on patient satisfaction. In part, we have objectified this satisfaction by the survey of the general population and interviews with satisfied patients, some of whom report impressive and rapid healing after many a long search for solutions in conventional medicine. However, it should be stressed that satisfaction is no guarantee of efficacy, in the strict sense, any more than it is of safety.

Even though homeopathy does not offer any inherent clinical efficacy, it may help physicians in catering medical assistance for patients in search of an alternative medical practice. They can do so without having to resort to prescription drugs. When applied by physicians, this approach offers the advantage of maintaining a therapeutic relationship without the risk of leaving the framework of conventional medicine.

#### 7.2 ENFORCING COLLA'S LAW?

In general, the key issue for the non-conventional forms of medicine enshrined in Colla's Law is to enforce this law.

As three-quarters of homeopaths are physicians, the problem does not arise for them. However, the current situation does pose a problem for non-physician homeopaths who are in fact practising illegally. This is especially the case where they prescribe remedies, which are legally considered to be medicines and whose prescription is therefore considered as a medical act (although, in early 2011, no homeopathic preparation is subject to prescription).

It is only if we agree to homeopathic practice being entrusted to non-physicians that the law needs to be enforced to cover this practice. But should we agree?

# 7.3 GUARANTEEING PATIENT SAFETY

Our study has shown clearly the wide range of problems for which homeopaths are consulted and their claims of therapeutic effects for this range of problems. However, as the efficacy of homeopathic treatments has not been scientifically proven, in many cases it will be necessary to resort to allopathic therapies. The fact that homeopathy is used as a complement or alternative to conventional medical treatment only reinforces the need for practitioners to have medical knowledge of diagnosis and conventional treatment.

In fact, for a primary-care provider with such a 'general practitioner' profile, it becomes difficult to distinguish the required competencies from those required of a physician.

Furthermore, many of the patients who turn to a non-physician homeopath have no idea whether or not they are consulting someone who has undergone another type of paramedical training.

In any event, in the case of homeopaths without a medical degree, the required competencies are by no means guaranteed, by either their training in homeopathy or their basic training. This entails a risk to the patient. In addition, these training courses are not currently subject to official external controls.

A further problem arises with physician homeopaths. Our study has shown that many continue to undergo training or retraining in the field of homeopathy but not in conventional medicine, with the risk that their knowledge is no longer up to date after a certain period.

The assertion that the practice of homeopathy leads to less misuse of such conventional medicines as antibiotics could not be verified for lack of usable data. Neither does literature provide a unanimous picture of the use of vaccines in the patient base of homeopaths.

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