



International Federation of Anthroposophic Medical Associations

# The legal status of anthroposophic medicine in selected countries

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## Introduction

The following document provides an overview of the legal status of anthroposophic medicine in selected countries.

Anthroposophic medicine is an integrative medical system founded in the early 1920's. It is practiced by physicians, in collaboration with nurses, pharmacists and psychologists, all of who are fully licensed in their country and have completed additional training in anthroposophic medicine.(1) Anthroposophic therapists in anthroposophic art therapy, eurythmy therapy and different anthroposophic body therapies have completed the respective anthroposophic training and may have a state diploma in art therapy, complementary therapy or other, depending on the country situation. Anthroposophic medicine is practiced in integration with conventional medicine in outpatient practices and hospitals.

The legal status and integration into national health system varies greatly between countries and is currently strongest in Brazil, Germany and Switzerland. Efforts and successes in obtaining official status in a given country have depended on factors such as government willingness to adopt such regulations, size of anthroposophic practitioner community, time since introduction of anthroposophic medicine in a country and possibility to practice anthroposophic medicine with or without official recognition.

For example, physicians in most countries can practice anthroposophic medicine under their general physician license even in absence of official recognition of the anthroposophic medicine training. The availability of anthroposophic medicinal products in a country, on the other hand, depends on appropriate regulation or, in the European Union, on the possibilities given by the European Union Directive 2001/83 EC; some countries may thus have specific regulations for anthroposophic medicinal products but may not yet have regulated anthroposophic health professionals (such as in Australia).

A detailed description of the regulatory situation of anthroposophic medicinal products (AMP) is beyond the scope of this paper and can be found elsewhere.(2-4) Many anthroposophic substances and manufacturing methods have been integrated into national pharmacopeias, often as homeopathic substances or manufacturing methods.(3) Some but not all AMP are manufactured according to homeopathic manufacturing methods; the regulation of AMP has therefore been linked to homeopathic regulations in some jurisdictions. It should be noted, however, that from a pharmaceutical point of view an AMP can be i) a herbal medicinal product, ii) a homeopathic medicinal product when manufactured according to an homeopathic manufacturing method, or iii) a specific anthroposophic preparation manufactured with specific anthroposophic manufacturing methods and leading to compositions of minerals, or plants and metals, for example. AMP's are distinct from homeopathic products, even if produced in the same way, because as they are developed and used based on the anthroposophic understanding of man and nature.

Anthroposophic medicine is practiced in 65 countries worldwide (<http://www.iva.info/anthroposophic-medicine/>).

We present here a selection of countries from the Americas, European and Western Pacific WHO regions where anthroposophic medicine has or is obtaining a degree of official status. This paper focuses on the legal and official

status and does not describe the extension in terms of practitioners, clinics and hospitals which has been described elsewhere.(5)

## Americas

### Argentina

#### *General legal and policy context*

A draft law on traditional and complementary medicine (Ley Nacional de Medicina Tradicional y Complementaria) is currently under consideration in the national legislative chamber. The law would provide recognition and regulation for complementary and traditional medicine with specific recognition of anthroposophic medicine.

#### *Health insurance coverage*

Specific reimbursement for anthroposophic medical services only occurs exceptionally. Anthroposophic medicinal products are not reimbursed.

#### *Recognition of training*

There is no official recognition of anthroposophic medicine training so far. The Argentine Medical Association (AMA) regularly teaches a post-graduate course on integrative medicine including a module on anthroposophic medicine.

#### *Status of anthroposophic medicinal products*

Anthroposophic medicinal products (AMP) can be registered as herbal medicines, as was done for an anthroposophic mistletoe product in 2013. Resolution N° 1817/2013 of the Ministry of Health authorizes the national drug regulatory agency (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica - ANMAT) to regulate herbal medicines. ANMAT Disposition 5418/2015 further defines the regulation of herbal medicines and herbal medicines for traditional use. There are no specific regulatory procedures for anthroposophic medicines; a negative list (ANMAT Disposition 1788/2000) excludes a number of plants used for AMP; current regulation also prevents registration of AMP produced by homeopathic methods.

#### *Academia*

A postgraduate course in anthroposophic medicine is taught at the National University of Rosario; a postgraduate course at the University of Buenos Aires is awaiting approval.

### Brazil

#### *General legal and policy context*

The practice of anthroposophic medicine was first acknowledged by the Brazilian Federal Medical Board's Opinion 21/93 of 23 November 1993.

Anthroposophic medicine is one of the five therapy systems of the Ministry of Health of Brazil "National Policy on Integrative and Complementary Practices of

the SUS (Unified Health System)" (PNPIC), adopted by Ministerial Rules No. 971 of May 3, 2006 and No. 1600 of July 17, 2006.

The five therapy systems included in the PNPIC are: Anthroposophic Medicine, Traditional Chinese Medicine - Acupuncture; Homeopathy; Medicinal Plants and Phytotherapy; Social Thermalism/Crenotherapy.

#### *Health insurance coverage*

Anthroposophic physician services are reimbursed as regular physician services. There is no specific reimbursement for anthroposophic services or anthroposophic medicinal products.

#### *Recognition of training*

The Brazilian Ministry of Labor and Employment lists *Anthroposophic doctor* as a profession (item 2251-54).

The Federal Council of Dentistry of Brazil recognized *Anthroposophic Dentistry* as a supplemental qualification (resolution CFQ 165/2015 from 24 November 2015).

The Federal Council of Pharmacy of Brazil recognized the *Anthroposophic Pharmacist* as a specialization of their profession (Resolution N°465 from 24 July 2007).

The Federal Council of Physiotherapy and Occupational Therapy of Brazil recognized *Anthroposophic Physiotherapy* as a supplemental qualification in 2010.

#### *Status of anthroposophic medicinal products*

The Brazilian Health Surveillance Agency (ANVISA) resolution RDC N° 26 from 30 March 2007 on the "*registration of industrialized, dynamized homeopathic, anthroposophic and antihomotoxic drugs*" provides a definition of anthroposophic medicines, refers to the Anthroposophic Pharmaceutical Codex(2) and provides registration procedures for anthroposophic medicines.

#### *Academia*

ABMA, the national association of anthroposophic physicians has cooperation and partnerships with the following universities: UNIFESP - University of São Paulo State (SP), University of Botucatu (SP), Unicamp – Campinas (SP), UFRJ - University of Rio de Janeiro, UFJF - University of Juiz de Fora (MG), University of SJDR (MG).

15 PhD theses and over 30 master theses in relation to anthroposophic medicine have been completed. 4 research projects in anthroposophic medicine receive funding from the Brazilian National Research and Technology Council.

## Europe

### Austria

#### *General legal and policy situation, and recognition of training*

The Austrian Medical Chamber (Österreichische Ärztekammer ÖÄK), which is responsible for medical licenses, issues post graduate physician “special diploma” (ÖÄK-Spezialdiplomen) in anthroposophic medicine and other complementary therapy systems.

#### *Health insurance coverage*

Anthroposophic physician services are reimbursed as regular physician services. There is no specific reimbursement for anthroposophic services or anthroposophic medicinal products.

#### *Recognition of training*

#### *Status of anthroposophic medicinal products*

Anthroposophic medicinal products are on the market through the national application of EU Directive 2001/83/EC (see description below for European Union).

#### *Academia*

No activities to report.

### Georgia

#### *General legal and policy context*

Georgia does not have a policy or laws on traditional and complementary medicine. A definition of anthroposophic medicinal products is provided in the Law of Georgia on Medicines and Pharmaceutical Activities, N° 1586 of 10 August 2009 (see below).

#### *Health insurance coverage*

There is no specific reimbursement for anthroposophic services or anthroposophic medicinal products.

#### *Recognition of training*

The postgraduate training curriculum in anthroposophic nursing and rhythmic massage is officially recognized by the Ministry of Education and Science.

#### *Status of anthroposophic medicinal products*

The Law of Georgia on Medicines and Pharmaceutical Activities, N° 1586 of 10 August 2009 defines in article 1, section 14: *“Complementary (homeopathic, anthroposophic, homotoxicological) medicinal product – a product prepared from substances or sum of substances from natural (mineral, plant or animal) origin, the effect and commonality of which has not been proven by objective evidence.”*

Article 11, section 20,h of the law establishes registration procedures for complementary medicinal products *“based on the curative principles of complementary medicinal products, substantiation of their effect and designation”*.

### **Academia**

No activities to report.

## **Germany**

### **General legal and policy context**

The German Medicine Act (Arzneimittelgesetz or ‘AMG’) recognizes anthroposophic medicine as one of the three ‘particular therapeutic systems’ (the two other are phytotherapy and homeopathy) (for details see below).

The German "Social Code - Book V - Statutory Health Insurance" (Sozialgesetzbuch V or 'SGB V'): Section 34 (3) SGB V specifically refers to homeopathic, phytotherapeutic and anthroposophic medications as belonging to the particular therapeutic systems.

### **Health insurance coverage**

The German "Social Code - Book V - Statutory Health Insurance" (Sozialgesetzbuch V or 'SGB V'): Section 2(1) states that "*particular therapeutic systems*" ("*besondere Therapierichtungen*") are not to be excluded from statutory health insurance coverage.

Anthroposophic hospitals, i.e. hospitals integrating conventional and anthroposophic medicine are reimbursed based on the German Disease Related Group (DRG) system with additional reimbursement codes for anthroposophic therapies.

Anthroposophic physician outpatient services are reimbursed as regular physician services; some health insurances reimburse specific anthroposophic therapies and medications as part of an integrative care coverage.

### **Recognition of training**

There is no official recognition of anthroposophic physician training. The medical school at Witten/Herdecke University offers integrated conventional and anthroposophic medicine training, leading to the state medical examination (see under academia below).

Two nursing schools, at the Herdecke Community Hospital and the Filderklinik Hospital, teach an integrated curriculum of conventional and anthroposophic nursing; they are recognized as nursing schools leading to the state nursing exam.

Master of Arts degrees in eurythmy therapy and art therapy are awarded at Alanus University (see below).

### **Status of anthroposophic medicinal products**

Section 4(33) of the German Medicine Act (Arzneimittelgesetz or ‘AMG’) defines anthroposophic medicinal products: *“An anthroposophic medicinal product is a medicinal product that has been developed according to the anthroposophic*

*knowledge of man and nature and that is manufactured according to homeopathic manufacturing procedure described in the European Pharmacopoeia or in absence thereof in a pharmacopoeia officially used in the Member States or according to a special anthroposophic manufacturing procedure and that is meant to be used according to the anthroposophic principles concerning man and nature.”*

Sections 25(6) and (7) AMG require the German Federal Institute for Drugs and Medical Devices ('BfArM') to consult expert commissions for the “*particular therapeutic systems*” before adopting marketing authorization decisions for a medicinal product attributed to one of special therapeutic systems; Commission C deals with anthroposophic medicinal products and consists of experts in anthroposophic medicine.

Anthroposophic medicinal products have a marketing authorization or a registration according to the German Medicines Act, which takes into consideration the long traditional use of these preparations.

### **Academia**

There is a university chair in anthroposophic medicine at Witten/Herdecke University; an adjunct professor of anthroposophic medicine at the Humboldt University–Charité Berlin as well as professors with specialization in anthroposophic medicine at Freiburg University, Bonn University and the Alanus University.

At Witten/Herdecke University, the “Integrated Curriculum for Anthroposophic Medicine”, a full training program in anthroposophic medicine is taught in integration with the 6-year medical school curriculum. Anthroposophic medicine is taught to medical students as part of complementary medicine at several universities.

Post-graduate courses are recognized in the Continuing Medical Education (CME) system for physicians

Scientific degrees (Dr. med, habilitation) have been obtained on anthroposophic medicine topics over several decades.

Master of Arts degrees in Eurythmy therapy and in Art therapy (integrating anthroposophic and classic art therapy) are awarded at the Alanus University of Arts and Social Sciences.

### **Hungary**

#### **General legal and policy situation**

Law “11/1997. (V. 28.) NM rendelet” on “naturopathic” medicine foresees that complementary medicine, including anthroposophic medicine, is to be practiced by physicians and states that naturopaths should learn about anthroposophic medicine in their training.

#### **Health insurance coverage**

Anthroposophic physician services are reimbursed as regular physician services. There is no specific reimbursement for anthroposophic services or anthroposophic medicinal products.

### **Recognition of training**

The Faculty of Health Sciences of Pècs University issues the degree of “Doctor of Anthroposophic Medicine” as a post-graduate degree for physicians. Based on this degree, the National Institute for Quality and Organizational Development in HealthCare and Medicine (GYEMSZI) and the Health Authority (ÁNTSZ) which is responsible for physician practice licenses, issues a license to practice as “*Anthroposophic Doctor*”, “*Anthroposophic Dentist*” or “*Anthroposophic Pharmacist*” (depending if the candidate is a licensed physician, dentist or pharmacist).

### **Status of anthroposophic medicinal products**

Anthroposophic medicinal products are prepared as magistral preparations by designated pharmacies so far as their substances are registered in the adequate Hungarian regulation. All other anthroposophic medicinal products can be imported from other EU countries on common personal admission.

### **Academia**

Anthroposophic medicine is taught in collaboration with the department of complementary medicine, faculty of Health Sciences, Pècs University.

Post-graduate courses are recognized in the CME-system for physicians and other health care workers.

Research and the possibility of attaining a scientific degree in the field of anthroposophic medicine (Ph.D., habilitation) is possible at the Doctorate School of the faculty of Health Sciences, Pècs University.

## **Italy**

### **General legal and policy situation, and recognition of training**

The “Permanent State-Regions-Autonomous Provinces Conference” adopted an agreement on 7<sup>th</sup> February 2013 concerning the criteria and accreditation modalities for training of physicians, dentists, veterinarians and pharmacists in acupuncture, phytotherapy and homeopathy (Rep. Atti n. 54/CSR). This agreement has the force of law at national level.

The Ministry of Health published a “note of clarification” (“nota di chiarimenti”) on the above agreement on 24<sup>th</sup> July 2014: this note clarifies that anthroposophic medicine is included in the agreement and states that the Italian regions should establish accreditation mechanisms for the concerned therapies (by decree or law). Currently, regions are preparing such legislation.

The Italian Federation of Medical Orders (FNOMCeO - Federazione Nazionale degli Ordini dei Medici Chirurghi et degli Odontoiatri) recognized anthroposophic medicine as one of nine complementary medicine systems (medicine non convenzionali) in 2002 (Trattato di Terni 2002).

The anthroposophic art therapy school “Cinabro” prepares students to obtain official accreditation as art therapist through the Italian Federation of Certification Associations (FAC, Federazione delle Associazioni per la Certificazione) which applies norm “UNI 11592:2015 Non-Regulated

Professions - Art Therapy Professionals - Knowledge, Skill And Competence Requirements”, under the law on non-regulated professions (legge 14 gennaio 2013, n. 4).

#### *Health insurance coverage*

Anthroposophic medicine is not covered by the National Health Insurance scheme (Servizio Sanitario Nazionale).

#### *Status of anthroposophic medicinal products:*

Italy regulates anthroposophic medicinal products through the legislative decree L.D. 219/2006 which is the national application of EU Directive 2001/83/EC. Medicines in low homeopathic potencies (including injections) already notified and on the Italian market for several years can be registered until June 2017 by a simplified procedure with safety justification and with a proof of the clinical tradition. Italy has not set up any specific rules for anthroposophic medicines not manufactured according a homeopathic manufacturing method.

#### *Academia*

Anthroposophic medicine is not taught at universities in Italy.

## **Latvia**

#### *General legal and policy situation*

See training.

#### *Recognition of training*

Government rule N° 317 on medical professions, specialties and medical procedures, in its amendment adopted by the Council of Ministers on 24<sup>th</sup> May 2016, recognizes anthroposophic medicine as a complementary diagnostic and therapeutic method (certified medical method N° M67).

The Latvian anthroposophic physician association (Latvijas Antroposofo Ārstu asociācija) is a member of the Latvian Medical Association (Latvijas Ārstu biedrība) which is responsible for medical licenses.

#### *Health insurance coverage*

Anthroposophic physician services are reimbursed as regular physician services. There is no specific reimbursement for anthroposophic services or anthroposophic medicinal products.

#### *Status of anthroposophic medicinal products*

See description below for European Union.

#### *Academia*

No activities to report.

## Sweden

### *General legal and policy situation*

There are no policies or laws on traditional and complementary medicine.

The “Vidarkliniken”, an anthroposophic integrative hospital and outpatient clinic outside Stockholm operates under supervision of the National Board of Health and Welfare (Socialstyrelsen).

### *Health insurance coverage*

Various county councils (landstingen) have concluded care agreements (vårdavtal) with the “Vidarkliniken”, covering anthroposophic inpatient and outpatient treatment expenses. The two largest county councils, Stockholm and Göteborg, have announced that they will not extend their care agreements for inpatient treatment in 2017 (Stockholm maintains both outpatient and inpatient cancer rehabilitation); this puts the the “Vidarkliniken” at significant financial risk.

### *Recognition of training*

There is no official recognition of trainings in anthroposophic medicine.

### *Status of anthroposophic medicinal products*

Market authorization for herbal medicinal products, traditional herbal medicinal products and natural remedies can be obtained in accordance with European directive 2001/83/EC. Homeopathic medicinal products must be registered at the Medical Products Agency in accordance with articles 14 and 15 of EU directive 2001/83/EC. At the moment there is no possibility to register products according to Art. 16.2 of the Directive 2001/83/EC.

Since 1993 the government had granted the anthroposophic hospital, the “Vidarkliniken” permission to sell certain anthroposophic medicinal products, with a specific mention of anthroposophic medicinal products in article 5, second paragraph of the Medicinal Products Act (Läkemedelslag 2015:315). This special permission will end on 1<sup>st</sup> July 2018, followed by a three-year transition period.

Anthroposophic medicinal products that are herbal medicines can be registered either as traditional herbal medicinal products - according to the Directive 2004/24/EC amending Directive 2001/83/EC as regards traditional herbal medicinal products - or as well established used medicinal products. Some of these herbal AMP's have a marketing authorization, e.g. a mistletoe preparation.

### *Academia*

Various studies on anthroposophic medicine have been carried out in collaboration with the Karolinska Institute Stockholm as well as Linköping University and were published in high impact journals. A study on anthroposophic mistletoe therapy in pancreatic cancer is currently underway at the Karolinska University Hospital.

## Switzerland

### General legal and policy situation

Complementary medicine was included in the Federal Constitution of the Swiss Confederation in 2009 following a popular vote with 67% of votes in favor of the popular initiative “Yes to complementary medicine”. Art. 118a 52 states: *“The Confederation and the Cantons shall within the scope of their powers ensure that consideration is given to complementary medicine.”*

The legally binding Federal Council Dispatch 06.660 from 30<sup>th</sup> August 2006 concerning the popular initiative “Yes to complementary medicine” specifically included anthroposophic medicine: *“The reimbursement for physician services in anthroposophically enlarged medicine, homeopathy, phytotherapy, neural therapy and traditional Chinese medicine shall be included definitively into the statutory health insurance as well as in other social insurances.”*

In 2006 a health technology assessment on anthroposophic medicine was compiled as part of the Complementary Medicine Evaluation Program (PEK) and financed by the Swiss Federal Office for Public Health (FOPH).(6) An update was published in 2011.(7)

### Health insurance coverage

The ordinance of the Federal Department of Home Affairs about the coverage of the compulsory basic health insurance scheme (Verordnung des EDI über Leistungen in der obligatorischen Krankenpflegeversicherung - Krankenpflege-Leistungsverordnung, KLV), in section 10 on complementary medicine, establishes coverage for anthroposophic medicine provided by physicians that hold the title *“physician for anthroposophic enlarged medicine”* until 31<sup>st</sup> December 2017. An amendment to the ordinance on health insurance (Verordnung zur Krankenversicherung 832.102 KVV), article 35a is expected to make the coverage for complementary medicine by the compulsory basic health insurance permanent in 2017.

TarMed, the current tariff system for all physicians in Switzerland has established tariffs for ambulatory consultations in anthroposophic medicine. SwissDRG which defines tariffs for inpatient treatment includes tariffs for anthroposophic medicine.

Anthroposophic therapies that are not provided by physicians can be reimbursed through private complementary insurances.

### Recognition of training

The Swiss Medical Association (FMH – SIWF), which regulates physician specialty titles in Switzerland, awards the title (certificate of competence – Fähigkeitsausweis) of *“physician for anthroposophically enlarged medicine”* in cooperation with the Swiss association of anthroposophic physicians (VAOAS).

Further education in anthroposophic pharmacy is recognized by the Swiss Pharmacist’s Association (Pharmasuisse) and pharmacists can get credit points for their continuous training in anthroposophic pharmacy.

Eurythmy therapy is a recognized orientation for the federal diploma in complementary therapy (KomplementärTherapeutin) - <http://www.oda-kt.ch/methodenanerkennung/>

Students at schools for anthroposophic art therapy in Switzerland obtain both the federal diploma in art therapy as well as a specific diploma in anthroposophic art therapy. Both diploma are recognized by complementary health insurances.

### *Status of anthroposophic medicinal products*

The Federal Act on Medicinal Products and Medical Devices has been revised in March 2016 and will come into force end 2018.

The new version of the Federal Act provides a definition on complementary medicinal products, including anthroposophic medicinal products, with and without indication in article 4, a<sup>ter</sup> and a<sup>quarter</sup>: *“Complementary medicinal products with indication: medicinal products with an officially approved indication of use that are manufactured according to the manufacturing procedures of the complementary therapy system such as homeopathy, anthroposophic medicine or traditional Asian medicine and whose indication of use is defined according to the principles of the relevant therapy system.”*

The simplified authorization and registration procedure has also been defined in the new version of the Federal Act, whereas until now it was defined at the level of the Swissmedic ordinance concerning Complementary and Phytomedicines (Verordnung des Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung von Komplementär- und Phytoarzneimitteln vom 22.6.2006). This Swissmedic ordinance includes homeopathic, anthroposophic and Asian medicinal products and defines in Art. 4, 2 f: *“Anthroposophic medicinal product: Medicinal product, whose active substances are manufactured by a homeopathic manufacturing procedure described in the German Homeopathic Pharmacopoeia or in the British Homeopathic Pharmacopoeia or according to a special anthroposophic manufacturing procedure and that is formulated and developed according to the anthroposophic knowledge of man, animal, substance and nature and is meant to be used according to these principles.”*

The Swiss Pharmacopoeia has implemented two texts concerning anthroposophic pharmacy:

- In 2009 (Suppl. 10.1) with the general Ph.Helv.-monograph “Praeparationes anthroposophicae (Anthroposophic Preparations)” (Ph.Helv. CH 306). This monograph includes a definition of Anthroposophic Preparations: *“Anthroposophic preparations are developed, manufactured and composed according to the principles of anthroposophic knowledge of man, animal, substance and nature. They are meant to be used according to these principles. An Anthroposophic Preparation can contain one or more active substances and excipients. The active substances can be used concentrate or after being manufactured according to a manufacturing method used in anthroposophic Pharmacy.....”* “....Manufacturing methods used in Anthroposophic Pharmacy are either homeopathic manufacturing methods or anthroposophic manufacturing methods.” (See Chapter 17.7. Ph. Helv).
- In 2013 (Suppl. 11.1) the new Ph.Helv.-chapter “17.7 Manufacturing methods for anthroposophic preparations”.

Anthroposophic medicinal products without indication (the majority of AMP's) are included in the List of Pharmaceutical Specialties (Spezialitätenliste) which

guarantees their reimbursement through the compulsory basic health insurance scheme. A few standard anthroposophic preparations with indication and under prescription are also in the compulsory basic health insurance.

### **Academia**

The Federal Act on Medical Professions (Bundesgesetz über die universitären Medizinalberufe - Medizinalberufegesetz, MedBG), article 8 section j, states that graduates in human medicine, dentistry and chiropractic *“have adequate knowledge about methods and therapy systems of complementary medicine.”* Graduates in pharmacy need to have knowledge of complementary medicinal products (article 9 section i).

Based on this provision, Swiss medical schools provide introductory courses in complementary medicine for medical students, including an introduction on anthroposophic medicine. Swiss faculties of pharmacy provide introduction in complementary medicine for their students; phytotherapy, homeopathy and anthroposophic medicine are part of these curricula. Master thesis and PhD's in Pharmacy have been working with substances used in anthroposophic medicine.

The University of Berne has a full *“professor in anthroposophically enlarged medicine”* who is also co-chair of the university's Institute of Complementary Medicine – IKOM.

### **Regulation of Anthroposophic Medicinal Products by the European Union**

The European Union has repeatedly confirmed that it is up to each member state to organize and regulate their health care system. It therefore has not issued policies on complementary medicines.

Medicinal products, however, are not defined as a part of health policy and are regulated at the EU level.<sup>(3)</sup> Anthroposophic medicinal products (AMP) are recognized but not specifically regulated by the EU. AMP can benefit from a simplified registration procedure if they qualify as homeopathic or traditional herbal medicinal products as laid out in Directive 2001/83/EC, specific chapters on homeopathic medicinal products (Article 13-16) and herbal medicinal products (Article 16a-16i).

Unfortunately, several Member States have not implemented article 16.2 preventing anthroposophic medicinal products not complying with article 14 (concerning homeopathic products) from entering the market.

In any case, Directive 2001/83/EC does not include all AMP. Directive 2001/83/EC, recital 22 states: *“The anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorization, in the same way as homeopathic medicinal products.”* While this expressly recognizes anthroposophic medicinal products, it does not sufficiently define them: not all anthroposophic products follow homeopathic manufacturing methods and not all anthroposophic active substances are described in the European Pharmacopoeia or in a national pharmacopoeia.<sup>(3)</sup>

## Western Pacific

### Australia

#### *General legal and policy situation*

There is no official recognition of anthroposophic medicine. Anthroposophic medicinal products are covered by the Australian regulatory guidance (see below).

#### *Health insurance coverage*

Anthroposophic physician services are reimbursed as regular physician services. There is no specific reimbursement for other anthroposophic services or anthroposophic medicinal products.

#### *Recognition of training*

There is no official recognition of anthroposophic medical trainings in Australia. Anthroposophic medicine is listed as a system of integrative medicine with the Australasian Integrative Medicine Association.

#### *Status of anthroposophic medicinal products*

The “Australian regulatory guidelines for complementary medicines ARGCM”, Version 6.0 from October 2016 also applies to anthroposophic medicinal products. It states: “*Anthroposophic medicines: Anthroposophic practitioners use a range of interventions including conventional therapies, remedies based upon homoeopathic principles, herbal medicine and external therapies.*”

#### *Academia*

Courses in anthroposophic psychotherapy are taught at Edith Cowan University.

### New Zealand

#### *General legal and policy situation*

Anthroposophic medicine is not officially registered in New Zealand. Physicians practicing complementary medicine are guided by the guidelines of the Medical Council of New Zealand (Statement on Complementary and Alternative Medicine 2011). The “New Zealand Association of Anthroposophic medicine NZAAD” is a registered peer group with the Royal New Zealand College of General Practice. Some NZAAD members are also members of AIMA, the Australasian Integrative Medicine Association which is a registered provider with the Royal New Zealand College of General Practice.

#### *Health insurance coverage*

Anthroposophic physician services are reimbursed as regular physician services under customary private health insurance. There is no specific reimbursement for other anthroposophic services or anthroposophic medicinal products.

### *Status of anthroposophic medicinal products*

Anthroposophic medicinal products are registered as medicines with the New Zealand medicines authority Medsafe.

### *Academia*

No activities to report.

## **Philippines**

### *General legal and policy situation*

The "Traditional and Alternative Medicine Act (TAMA) of 1997" regulates traditional and complementary medicine; it has no specific mention of anthroposophic medicine. The Philippino Institute of Traditional and Healthcare (PITAHC) is the government institute under the department of health mandated to implement the provisions of this law.

### *Health insurance coverage*

Anthroposophic physician services are reimbursed as regular physician services. There is no specific reimbursement for other anthroposophic services or anthroposophic medicinal products.

### *Recognition of training*

The Philippino Institute of Traditional and Healthcare PITAHC is currently working with representative of anthroposophic medicine to create competency standards for anthroposophic medicine.

### *Status of anthroposophic medicinal products*

There is no specific regulation for anthroposophic medicinal products.

### *Academia*

Fundamental concepts of human nature from the perspective of anthroposophic medicine are taught at West Visayas State University, College of Medicine, integrated into the general medical curriculum.

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