

Medical Section for Anthroposophic Medicine

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and

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To

Directorate-General for Health and Consumers

Unit SANCO/D/5

BE-1049 Brussels

Herdecke/Dornach, 2012/11/24

Subject: Comment on the PCPD/12/01 — Public Consultation on paediatric report

To Whom It May Concern,

The Medical Section for Anthroposophic Medicine and the pediatric department of the biggest Anthroposophic Hospital in the world want to comment on one point of your public consultation about ARTICLE 50(2) OF REGULATION (EC) NO 1901/2006.

CONSULTATION TOPIC: 12. ANY OTHER ISSUE?

Consultation item No 12: Overall, does the implementation of the Regulation reflect your initial understanding/expectations of this piece of legislation? If not, please precise your views. Are there any obvious gaps with an impact on paediatric public health needs?

As representatives for Anthroposophic Medicine in Pediatrics we found the gap of not being named in this regulation same as homeopathic medicinal products and traditional herbal medicinal products in the eleventh paragraph of the regulation where it says:

“However, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic medicinal products and traditional herbal medicinal products authorised through the simplified registration procedures of Directive 2001/83/EC of the European Parliament and of the council of 6 November 2001 on the Community code relating to medicinal products for human use. OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).”

Although Anthroposophic Medicine uses homeopathic and traditional herbal medicinal products there are some progressions and additional elements like mistletherapy which differ. Because of our long tradition of more than 90 years in which we are using Anthroposophic remedies in the treatment of children not only in Europe, but all over the world we have rich experience of a high safety and efficacy even in critically ill children. In our hospital in Herdecke we use the integrative Anthroposophic Medicine and medicinal products for children without any undesirable effects since more than 40 years! There are studies about our specific treatments, especially numerous about the use of mistletherapy in cancer patients. An overview to history, treatment and study results gives the book: *Die Mistel in der Onkologie – Fakten und konzeptionelle Grundlagen*. G.S. Kienle, H. Kiene. Schattauer Verlag; 2003, Stuttgart, New York.

One of our initiatives already works on the acknowledgement of Anthroposophic Medicinal Products in general:

ESCAMP - European Scientific Cooperative on Anthroposophic Medicinal Products

ESCAMP aims to develop the scientific basis for a permanent regulatory framework for anthroposophic medicinal products (AMPs) in Europe. This includes the following tasks:

1. Development of methods and standards for the scientific assessment of efficacy/effectiveness, safety and cost-effectiveness of AMPs.
2. Elaboration of appropriate categories and criteria for regulatory assessment of AMPs, which could be implemented in a draft law for registration of AMPs in Europe.
3. Implementation of these methods and regulatory criteria in registration documents and product monographs.

Foundations for this work have been developed during the past 10 years:

- the Anthroposophic Pharmaceutical Codex [1]
- a growing body of clinical research and reviews on Anthroposophic Medicine (e. g. mistletoe reviews, AMOS study, IIPCOS study [2-7])
- the first comprehensive review of clinical studies of Anthroposophic Medicine in a health technology assessment report [8]
- the pharmacovigilance network EvaMed (Evaluation of Anthroposophic Medicine) [9]
- the concept of Cognition-based Medicine [10]
- the Vademecum of Anthroposophic Medicines [11]

for further information see: <http://www.escamp.org/aims-task-and-prerequisites.html>

In Herdecke one of our specialties is to use integrative medicine in the treatment of children with cancer. The following study shows the frequent use of anthroposophic and other complementary methods in pediatric oncology: (published e.g. in: *Pediatr Blood Cancer*. 2010 Dec 1;55(6):1111-7.)

Anthroposophic medicine in paediatric oncology in Germany: results of a population-based retrospective parental survey. Läengler A, Spix C, Edelhäuser F, Martin DD, Kameda G, Kaatsch P, Seifert G.

Source: Gemeinschaftskrankenhaus Herdecke, Department of Paediatric and Adolescent Medicine, Herdecke, Germany. a.laengler@gemeinschaftskrankenhaus.de

ABSTRACT:

Background: Anthroposophic medicine (AM) is frequently utilised in German-speaking countries as a complementary and alternative medicine (CAM) treatment approach.

Procedure: This study presents results of a retrospective parental questionnaire comparing responses of AM-users and users of other CAM in paediatric oncology in Germany. The differences between these two groups are investigated with respect to usage, associated demographic characteristics and previous experience with CAM.

Results: Ninety-eight patients (27%) of the 367 CAM-users were exposed to anthroposophic treatments or therapies. Treatment duration amounted to a median 619 days for AM and 225 days for other CAM treatments. Most parents with previous experience of AM also used AM for treatment of their child's cancer

disease. AM-users had a higher social status. Physicians played a relevant role for users of AM both in procuring information (24% vs. 11%; $P < 0.001$) and in prescribing medicines and therapies (73.0% vs. 34.9%; $P < 0.001$) compared to users of other CAM. AM-users communicate more frequently with their physicians about the use of CAM treatments (89.8% vs. 63.9%) and recommend CAM more often than other CAM-users (95.9% vs. 87%).

Conclusions: AM plays a major role in paediatric oncology in Germany. Patients using AM sustain treatment and therapies considerably longer than patients using other CAM treatments. Furthermore, most families who had used AM before their child was diagnosed with cancer also used AM for the treatment of their child's cancer. Compared to other CAM treatments, patient satisfaction with AM appears to be very high.

There is a large number of other studies, case reports, articles and books where our experience and the scientific background of Anthroposophic Medicine in childhood is well documented. (please see list below)

So we are sure we should be named in this 11th paragraph to prevent unnecessary costs and studies to proof the safety and efficacy of our medicinal products again.

On behalf of the Medical Section and the Pediatric Department of the Community Hospital in Herdecke,

Dr. med. Michaela Glöckler

Prof. Dr. med. Alfred Längler

Head of the Medical Section

Head of the Pediatric Department

Selected Books:

Das Kinder Gesundheitsbuch. Jan Vagedes, Georg Soldner. Gräfe und Unzer Verlag, München (2008).

Die Mistel in der Onkologie – Fakten und konzeptionelle Grundlagen. Gunver S. Kienle, Helmut Kiene. Schattauer Verlag, Stuttgart, New York (2003).

Individuelle Pädiatrie. Leibliche, seelische und geistige Aspekte in Diagnostik und Beratung. Anthroposophisch-homöopathische Therapie. Georg Soldner, Hermann Michael Stellmann. 4. Aufl. Wissenschaftliche Verlagsgesellschaft, Stuttgart (2011).

Kindersprechstunde. Wolfgang Goebel, Michaela Glöckler . 18., erneut überarbeitete Aufl. Urachhaus, Stuttgart (2010).

Komplementärmedizin für Kinder. Michaela Glöckler. Kap. Beratungsempfehlungen aus der Anthroposophischen Medizin. Wissenschaftliche Verlagsgesellschaft, Stuttgart (2012)

Selected literature:

Hamre HJ, Witt CM, Kienle GS, Meinecke C, Glockmann A, Willich SN, Kiene H. Anthroposophic therapy for children with chronic disease: a two-year prospective cohort study in routine outpatient settings. BMC Pediatrics 2009, 9 (39). DOI 10.1186/1471-2431-9-39

Heusser PH. Akademische Forschung in der Anthroposophischen Medizin. Beispiel Hygiogenese: Natur- und geisteswissenschaftliche Zugänge zur Selbstheilungskraft des Menschen. Peter Lang AG, Bern (1999).

Kienle G. The story behind mistletoe: A European remedy from anthroposophical medicine. *Alternative Therapies* 5(6):34-36 (1999).

Kienle G. Anthroposophische Medizin. In: Wörterbuch medizinischer Grundbegriffe (Ed. E. Seidler). Herder Verlag, Freiburg, Basel, Wien (1979).

Kienle GS, Kiene H, Albonico HU. Health Technology Assessment, Bericht Anthroposophische Medizin. Erstellt im Rahmen des Programm Evaluation Komplementärmedizin (PEK) des Schweizer Bundesamtes für Sozialversicherung. 2005.

Kienle GS, Kiene H, Albonico HU. Anthroposophische Medizin in der klinischen Forschung. Wirksamkeit, Nutzen, Wirtschaftlichkeit, Sicherheit. Schattauer Verlag, Stuttgart, New York (2006). (Kienle GS, Kiene H, Albonico HU. Anthroposophic Medicine: Effectiveness, Utility, Costs, Safety, Schattauer Verlag, Stuttgart, New York (2006)).

Längler A, Spix C, Seifert G, Gottschling S, Graf N, Kaatsch P. Complementary and alternative treatment methods in children with cancer: a population-based retrospective survey on the prevalence of use in Germany. *European Journal of Cancer* 44(15):2233–2240 (2008).

Längler A et al. Anthroposophic medicine in paediatric oncology in Germany: Results of a population-based retrospective parental survey. *Pediatr Blood Cancer* 2010; 55(6):1111-1117

Matthiessen, P. F. Grundprinzipien einer salutogenetischen Medizin. www.hauptstadtkongress.de/2002/referate/Matthiessen.pdf (2002).

Seifert G, Rutkowski S, Jesse P, Madeleyn E, Reif M, Henze G, Längler A. Anthroposophic Supportive Treatment in Children With Medulloblastoma Receiving First-line Therapy. *J Pediatr Hematol Oncol* 33(3):105-108 (2011)

Steiner R. Grundlegendes für eine Erweiterung der Heilkunst nach geisteswissenschaftlichen Erkenntnissen. Rudolf Steiner Verlag, Dornach (1991).

<http://wissenschaft.mistel-therapie.de/>

<http://www.escamp.org/aims-task-and-prerequisites.html>