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Report Information Session on Anthroposophic Medicine

EMEA, London
6 March 2008

On 6 March 2008, the Committee on Herbal Medicinal Products (HMPC) attended an 'information session' on anthroposophic medicine organised in cooperation with the Association Européenne des Fabricants de Médicaments utilisés en Thérapeutique Anthroposophique (AEFMUTA).
As outlined by the European Commission[1], anthroposophic medicines have had a long tradition in Europe for decades. Some anthroposophic medicinal products may be eligible for the simplified registration procedure for homeopathic medicinal products or under the simplified registration procedure for traditional herbal medicinal products. However, some anthroposophic medicinal products do not fulfil the required conditions for eligibility to these registration procedures. The European Commission was of the view that the extension of the simplified registration procedure to other products than herbal substances with a long tradition of safe use could be considered and anthroposophic medicines were included in the examples of medicinal products for which such an extension was proposed.

The above-mentioned 'information session' was organised with a view to allowing HMPC members to gather specific information on anthroposophic medicine and its approach.
Similar initiatives might be taken in the future in the area of Ayurveda and traditional Chinese medicine.

The programme of the 'information session' is provided in the annex to this report.
The session included presentations by representatives from three international/European Associations:
- AEFMUTA, Association Européenne des Fabricants de Médicaments utilisés en Thérapeutique Anthroposophique
- IAAP, International Association of Anthroposophic Pharmacists
- IVAA, International Federation of Anthroposophic Medical Associations

Introduction by the Chair

Nand De Herdt thanked the Committee for the opportunity to provide information on anthroposophic medicine. He highlighted that, because of the specificity of the anthroposophic medical approach, some examples given during the information session could fall under the mandate of the HMPC whereas other examples covered other natural substances and other distinct manufacturing procedures (pharmaceutical processes). In addition, a considerable number of medicinal products needs the supervision of a medical doctor. He stressed that anthroposophic medicine is considered amongst its experts as an enlargement of conventional medicine. After this introduction, the following seven speakers gave their presentations.

[1] See draft European Commission communication to the Council and the European Parliament "Report on the experience acquired This event was organised with a view to informing HMPC members on other tradition as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to traditional herbal medicinal products", published on the Commission website on 30 May 2007. (http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_05/herbals_draft_report_2007_05_29.pdf)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Dr Peter Zimmerman (Finland) gave a general presentation on 'what is anthroposophic medicine' and its different therapies including medicinal treatment. He stressed that anthroposophic physicians have to be in the first place conventionally educated doctors, on the basis of which additional education and training in anthroposophic medicine may be added. He explained that anthroposophic education programs are based on strict quality criteria set up by the national 'Anthroposophic Medical Associations' covered by the IVAA.
He pointed out that anthroposophic medicine has a long tradition in a number of European Member States and it is nowadays integrated in general and specialised public healthcare in several Member States with a number of general public hospitals specialised in anthroposophic medicine. He also reported that 30.000 medical doctors in 18 EU Member States, Norway and Switzerland practice anthroposophic medicine. He concluded his presentation informing that anthroposophic medicine and anthroposophic medical treatments are also the first choice in 629 centres worldwide specialised in social therapy and curative education for children and adults with learning difficulties (including the Camphill institutes).

Dr Christiaan Mol (The Netherlands) and Dr Giancarlo Cimino (Italy) dealt in a joint lecture with the anthroposophic process approach for a plant material for which a draft HMPC monograph exists, Betulae folium, the birch. The specific approach they described comprised pharmaceutical and medical aspects. They explained the anthroposophic process correlation between human being/plant/pharmaceutical process focussing on "cold", "warmth" and "rhythm" elements as summarised in the following table:

	Human Being	**Plant**	**Pharmaceutical Process**
cold	Nerve sense system	root	e.g. cold maceration
rhythm	Rhythmic system	leaf	e.g. rhythmic application cold/heat
warmth	Metabolic systen	flower	e.g. decoction

They elaborated on the phenomenology of the processes - tendency to deposit and tendency to keep in solution - in the leaves and in the bark (cork) of the birch and the similar processes in the kidney leads via a different reasoning to the same traditional indication for the birch as described in the draft Community herbal monograph on Betulae folium: 'increase the amount of urine to achieve flushing of the urinary tract'.
They explained that fresh and young birch leaves are used in anthroposophic medicine for the treatment of sclerotic conditions as they are processed by a rhythmic process applying warmth and cold in aqueous phase.

They also presented a typical feature of anthroposophic pharmacology- bring different substances together in a "composition" by distinct processes - with the example of 'Carbo Betulae cum Methano'.

In their conclusion they stressed that anthroposophic pharmacology uses starting materials (from biodynamic cultivation in preference and in line with GACP), treated with coherently chosen pharmaceutical processes, in order to selectively stimulate the self healing forces of the patient. They highlighted that the basis of the anthroposophic pharmacology is a linked understanding between processes in nature, the functional level of the human being and pharmaceutical processes. They stressed that official international pharmacopoeias describe a number of these processes whereas the remaining specific methods are described in the 'Anthroposophic Pharmaceutical Codex' (APC). (http://www.iaap.org.uk/downloads/codex.pdf).

Dr Guus van der Bie (The Netherlands) presented the approach within anthroposophic medicine of hay fever and its treatment with a typical anthroposophic herbal medicinal product: a composition of lemon juice with quince extract available in the different administration forms, injections, eye drops and nasal spray. He described the clinical picture, how to integrate, starting from the anatomy of the human body and the vision on immunology, the conventional approach and the specific anthroposophic approach. In the anthroposophic approach of the patient and his disease, a loss of self-organisation, inflammatory processes, excessive humoral and mucus secretions and a deregulation of immune reactions are seen. After having discussed the therapeutic goals (reinforce the 'self' and balance the body fluids) and the therapeutic process (protecting against external influences and

structuring the excess of watery secretions), he explained the composition which is used in anthroposophic medicine to treat hay fever: two fruits, the lemon and the quince, show processes which are similar with the therapeutic processes of the dynamic approach: “making a skin” and “shaping the fluid” for the lemon and “structuring fluids” and “making wood-like protections of the content” for the quince. The combination Citrus/Cydonia (as injection and as nasal spray or eye drops) has been in use for many decades in anthroposophic medicine. First small scale studies in The Netherlands have shown the very significant improvement of the symptoms in patients. Additional studies are currently performed in order to confirm the safety and effectiveness of this typical anthroposophic medicinal product for hay fever.

Dr François Hibou (France) presented the development of a new anthroposophic medicinal product, using the example of a homeopathic composition for minor sleeping disorders which has been authorised as a homeopathic OTC medicinal product in France since 2005. He first described the anthroposophic perspective on the physiology of sleep, then the physiopathology of sleeping disorders, finally establishing correspondences between the pathological condition and natural medicinal substances. The specific anthroposophic ratio is based on the ‘threefoldness’ of the human organism: the nerve-sense system (highly conscious, associated with wakefulness), the metabolic-limbs system (unconscious) and the rhythmic system (emotionally conscious). Falling asleep is seen as release of the grip of the nerve-sense system on the other two functional systems. Sleeping disorders can be related to the excessive activity of the nerve-sense system itself or its excessive influence upon the other two systems. He explained the anthroposophic ratio of the choice of the three plants, of the specific parts of the plants (beans, stems/leaves and roots) and of the level of the potencies: Coffea Tosta D20 calms down the nerve-sense system (e.g. excessive alertness, hyper ideation), Valeriana radix D3 relieves excessive nerve-sense influence on the metabolic-limbs system (e.g. spasms, cramps, restless legs) and Datura Stramonium D12 frees the rhythmic system from excessive nerve-sense influence (e.g. emotions, nightmares, heart palpitations).
In a small first post-marketing clinical study with 61 patients the outcome was very positive in terms of the satisfaction rate of the patients, a general improvement of the sleep quality identified by the total score of the Spiegel sleep questionnaire and a significant improvement of sleep latency mainly in patients with a baseline sleep latency of more than 30 minutes.

Dr Thomas Breitkreuz (Germany) presented an outline on specific aspects of anthroposophic medicine in clinical settings with examples from his hospital and he demonstrated typical features of anthropsophic therapy for critically ill patients in the hospital. The approach is an ‘Integrative Medicine’ of anthroposophic therapies and conventional medicine, which he illustrated with treatment strategies for acute pneumonia including as well the quality assurance data which have been the outcome of a quality assessment program in 330 hospitals including about 50,000 patients. Although the start of antibiotic therapy in the first 8 hours has been much lower in the anthroposophic clinic in Herdecke than the average (54% against 88%), the clinical course was favourable and a very significant lower percentage of in-hospital mortality due to pneumonia has been observed (9,4% against 14,3% for the average of the 330 hospitals with a percentile of P90). The multimodal approach used in anthroposophic clinics can be conventional medical intervention, anthroposophic medication, nursing and physical therapies, art therapy and therapeutic eurythmy. For each patient an individual therapeutic strategy is elaborated and constantly adjusted. The speaker presented the example of the treatment of acute pneumonia with anthroposophic remedies in the acute phase, the phase of stabilisation and the recovery phase (with a total spectrum of about 40 different remedies) used on the basis of individual diagnosis combined (only if needed) in the acute phase with antibiotic therapy in case of positive criteria for severe sepsis.

Dr Harald Hamre (Norway) stressed in his introduction some of the major difficulties anthroposophic medicine has to overcome in the area of clinical research: the physician-patient relationship and the therapy preference of the patient that interfere with randomisation. This situation as well as the fact that the patient seeking anthroposophic therapy is not ready to accept the ‘risk’ to be part of the placebo group give as well recruitment problems for large randomised clinical trials (RCTs).
Nevertheless a large number of studies are done and the Health Technology Assessment report commissioned by the Swiss federal social insurance office and published in 2006 discusses 188

clinical studies on anthroposophic medicinal products, a large majority of 179 showing positive results. Dr Hamre went into the details of one of the studies, a comparative study on acute respiratory and ear infections; 1016 patients from anthroposophic or conventional physicians in 5 countries were included in the study comparing the outcome of anthroposophic treatment versus conventional treatment. In the anthroposophic treatment group 265 different anthroposophic remedies were prescribed. In this group very little antibacterials or analgesics were prescribed and very little anti-inflammatory agents or antihistamines. The anthroposophic group performed better in the 'time to first improvement', improvement in general and the 'time to complete recovery'. Also the patient satisfaction was higher in this group. Even after adjusting the outcomes for 7 relevant baseline variables all the adjusted odds ratios favoured anthroposophic treatment. Some additional studies were presented on the safety of anthroposophic medicinal products: the studies show that the medicinal products investigated are well tolerated and result in only few adverse drug reactions (ADRs) which mostly have a mild to moderate intensity. No risk has been found from the 'avoidance of necessary conventional treatment'. One other safety study covered a period of two years with 662 outpatients having used in that period 949 anthroposophic medicinal products for chronic indications. Again a low frequency of ADR was found and no serious ADR occured. Finally the future research planning will include RCTs, observational studies, methodology research and the evaluation of individualised anthroposophic therapy.

Closing remarks

In his closing remarks Nand De Herdt expressed his gratitude for the very high degree of interest and attention for the presentations and the constructive discussion.
The HMPC Vice-chair Dr Ioanna Chinou thanked the speakers and AFEMUTA for the excellent contributions and the instructive exchange of views and experiences.

ANNEX

HMPC Information Session on Anthroposophic Medicine

7, Westferry Circus, Canary Wharf, London E14 4HB
EMEA, conference room 3A, 3rd floor

6 March 2008, 9.00-13.00

PROGRAMME
Chair: Nand De Herdt

9.00 – 9.10 Welcome (*Dr Ioanna Chinou*)

9.10 – 9.40 The anthroposophic medical movement in Europe (*Peter Zimmermann MD, PhD, Gynaecologist and Obstetrician, President of the International Federation of Anthroposophic Medical Associations, IVAA)*
- Questions

9.40 – 10.20 The anthroposophic process approach towards medicinal products (*Christiaan Mol, Pharmacist, Member of theBoard of Management of the International Association of Anthroposophic Pharmacists IAAP and Giancarlo Cimino, MD, paediatrician, expert of the Italian Health Ministry for continuous medical education, Italy)*
- Questions

10.25 - 10.50 The anthroposophic physician and the patient (*Guus van der Bie, MD, General practitioner, Lecturer for CAM and Medical Humanities, Utrecht State University, Netherlands)*
- Questions

10.50 – 11.20 Coffee

11.20 – 11.45 The anthroposophic rationale in the development of a medicinal product, an actual example (*Dr François Hibou, AEFMUTA*)
- Questions

11.45 – 12.10 Anthroposophic medicines in clinical settings (*Thomas Breitkreuz, MD, PhD, Chairman of Commission C (BfArM), Specialist of Internal Medicine, Executive Physician, Dept. of Internal Medicine, Gemeinschaftskrankenhaus Herdecke, Germany*)
- Questions

12.10 – 12.35 Research into Anthroposophic Medicine: Past, Present, Future (*Harald J Hamre, MD, PhD, Previously general practitioner, Norway, presently Senior Researcher, Institute for Applied Epistemology and Medical Methodology, Freiburg, Germany)*
- Questions

12.35 – 12.50 Questions and final discussion

12.50 – 13.00 Closing remarks (*Dr Ioanna Chinou*)

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu