

base of these results even more samples could be analysed to validate the quality of a mixing process with NIRS instead of using time and solvent consuming HPLC. NIRS is meanwhile accepted as a method by the 4th edition of the European Pharmacopoeia.

Martin Diller from the German Federal Institute of Drugs and Medical Devices (BfArM) commented the new "Note for Guidance on the Use of Near Infrared Spectroscopy by the Pharmaceutical Industry and the Data Requirements for new Submissions and Variations CPMP/QWP/3309/01, Aug 2003". Up to now, no NIRS-method has been implemented in a dossier-application of a herbal medicinal product in Germany. However, there is no reason for not accepting an NIRS-method if it is justified and validated according to the rules. The discussion showed that the practical experience with NIRS is very different from company to company. In many companies the technique is used to approve identity of inactive ingredients, but not to control quality or processes. New efforts should be focused on making NIRS a reliable tool especially for expensive validation procedures – costs could probably be reduced remarkably. Furthermore, NIRS has a high potential in routine analyses as well, especially in analysing essential oils and water in extracts or herbal drugs. Water analyses have not been discussed and could be a topic for a future workshop. All presentations also at: [www.ga-online.org](http://www.ga-online.org)

Beat Meier, Chair of the permanent committee

### 3<sup>rd</sup> Mistletoe Symposium in Nonnweiler-Otzenhausen, 20–22 November 2003

#### *Mistletoe therapy: basic research and clinical practice*

From 20–22 November 2003, approximately 100 clinicians from various therapeutic fields and scientists from virtually every branch of medicine and pharmaceuticals met in Nonnweiler (Germany) to present and discuss the current state of basic research and the clinical use of mistletoe products in tumour therapy. Such a conference was only possible because it was sponsored and arranged by the Karl and Veronica Carstens Foundation and the Society of Anthroposophical Physicians in Germany (GAÄD), together with the Society for Medicinal Plant Research (GA), the Phytotherapy Society (GPhyt), the German Pharmaceutical Society (DPhG) and the Central Association of Physicians of Nature Medicine and Regulative Medicine (ZÄN). As in the two previous conferences, Dr. Rainer Scheer, of the Carl Gustav Carus Institute in Niefern-Öschelbronn, was responsible for the organisation. Further members of the scientific organising committee were Professors Bauer (Graz), Becker (Saarbrücken), Fintelmann (Hamburg), Kemper (Münster) and Schilcher (Munich).

This interdisciplinary symposium saw the continuation of a number of mistletoe symposia which have taken place every for years since 1995. They aim was to provide a meeting point and discussion forum for scientists and physicians from various therapeutic fields and scientific disciplines, allowing them regularly to take stock of currently available studies and data. Practicians can thus form an objective picture of the potential uses and limits of mistletoe and take fresh impetus from the symposium, in order to undertake new research. This, in turn, will provide convincing data for an improved and more objective dialogue between the physicians of traditional medicine and their colleagues from other specialised areas (anthroposophy, homeopathy and phytotherapy). During the three days of the symposium, the current state of knowledge was presented in nine review papers, 32 short papers and 13 posters. The packed and balanced programme allowed for lively and constructive discussion and included contributions to relevant topics ranging from biology, pharmacy, the effects of various ingredients and their interactions with one another, immunology and clinical aspects, to clinical studies and proof of efficacy. Of particular interest was the participation of a number of

young researchers, whose refreshing contributions helped to establish new perspectives. For some time now, the use of mistletoe in tumour therapy has not been restricted only to anthroposophical therapy. Many reports confirm more than 80 years of medical experience and the therapeutic benefit of mistletoe therapy, which also brings a quantifiable and statistically significant benefit in terms of the hard endpoints of cancer therapy, i.e., survival time and quality of life. The clinical studies, however, do not comply with the current requirements of Good Clinical Practice (GCP). Randomisation is seen as a problem when conducting such studies. Nevertheless, the safety of mistletoe is generally considered to be established. Numerous experimental studies have allayed the suspicion that mistletoe induces progression in some types of tumour. The experiments of a Munich working group could not be reproduced and on closer inspection, it became apparent that these early findings were mainly due to the fluctuations inherent in such biological tests. Large-scale, long-term studies in the therapy of patients with various tumour types (breast cancer, melanoma, malignant lymphomas) showed no tumour enhancement associated with mistletoe products.

All abstracts can be found at [www.mistelsymposium.de](http://www.mistelsymposium.de). The contributions are set to appear at the end of 2004 in the form of a book published by KVC Verlag, Essen. You are cordially invited to the 4<sup>th</sup> Mistletoe Symposium, which is planned for November 2006, i.e., in only three years time.

In conclusion, the approximately 100 scientists from virtually every branch of medicine and pharmaceuticals issued the Nonnweiler Declaration, in which they announced that, from the scientific and ethical point of view, it is vitally important that the statutory health insurance funds continue to refund the costs of all parenterally administered mistletoe products, both allopathic and anthroposophical. In the declaration, they demanded that the newly formed Federal Joint Committee should include mistletoe products used in tumour therapy in the so-called Exclusion List and they referred to the available scientific data. The following gives the exact wording of the Nonnweiler Declaration:

Ref.: § 34 (SGB\* V), in association with GMG\*\*;  
Directive §92 paragraph 1 – clause 2 – no. 6

#### **NONNWEILER DECLARATION**

The participants in the 3<sup>rd</sup> International Symposium "Mistletoe in tumour therapy – basic research and clinical practice" (20–22 November 2003, Nonnweiler) declare that, on the basis of the available results of scientific research and the new results announced and discussed in Nonnweiler, the parenteral administration of *allopathic* and *anthroposophical* mistletoe products fulfils the requirements of Directive §92 paragraph 1 – clause 2 – no. 6. The assembled representatives from the fields of medicine and pharmaceuticals, bearing in mind the ethical responsibility they bear to their patients who seek advice from them, demand the inclusion of mistletoe products in the so-called EXCLUSION LIST.

Signed in the name of the symposium participants by Prof. Dr. Rudolf Bauer, Society for Medicinal Plant Research (GA), Prof. Dr. Hans Becker, University of Saarland, Prof. Dr. Volker Fintelmann, Carl Gustav Carus Academy, Hamburg, Prof. Dr. Dr. h.c. mult. Fritz Kemper, Phytotherapy Society (GPhyt), Prof. Dr. Dr. h.c. Heinz Schilcher, Central Association of Physicians of Nature Medicine and Regulative Medicine (ZÄN), Dr. Henning Albrecht, Karl and Veronica Carstens Foundation, Dr. Matthias Girke, Society of Anthroposophical Physicians in Germany (GAÄD)

\* Social security code

\*\* Health System Modernisation Act

Dr. Rainer Scheer, Carl Gustav Carus Institute,  
Niefern-Öschelbronn