EUROPEAN CONFERENCE

Herbal Medicinal Products in Europe - Harmonisation Achieved?

13 - 14 November 2007, Berlin, Germany

SPEAKERS:

Dr Linda Anderson, MHRA, UK
Gauthier Caron, Merck Consumer Health Care, France
Dr Per Claeson, MPA, Sweden
Cornelia Höhne, Phytolab, Germany
Dr Werner Knöss, Federal Institute for Drugs and Medical Devices, Germany
Dr Rainer Kolkmann, Dr Kolkmann & Partner, Germany
Prof Dr Reinhard Länger, Austrian Medicines and Medical Devices Agency, Austria
Dr Friedrich Lang, Schwabe Phytopharmaceuticals, Germany
Dr P. M. Mrozikiewicz, Research Institute of Medicinal Plants, Poland
Dr Dick Middleton, MH Pharma, UK
Jürgen Petersen, IMS Health, Germany
Ursula Schäfer, DiapharmGruppe, Dr. Stefan Sandner, Germany

HIGHLIGHTS:

- Potential of Herbal Markets in Europe
- Quality Requirements from a Regulator’s View
- Experiences with Marketing Authorisation and/or Traditional Registration in
  - Austria
  - France
  - Germany
  - Poland
  - Sweden
  - United Kingdom
- CTD Dossiers for Herbal Medicinal Products
- Ph.Eur. Monographs – Problems and Challenges
- Reference Substances
  - Selection
  - Classification
  - Characterisation
- Impact of the New European Health Claims Regulation
Herbal Medicinal Products in Europe – Harmonisation Achieved?
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Objectives

The aim of this conference is to give an overview what applicants really need in order to achieve a marketing authorisation in Europe. Participants can discuss with experienced representatives from European regulatory bodies and with speakers from industry how to overcome hurdles and to minimise costly registration delays. Nearly four years after Directive 2004/24 EC came into force and two years after implementation in national law had to be completed, first experiences with this new “tool” have been made in several countries. So this conference is a good chance to reflect on progress and to discuss further needs for improvement and harmonisation.

Background

Herbal Medicinal Products are in the focus of European consumers. The work of the Committee on Herbal Medicinal Products (HMPC) is in progress, a lot of guidance documents and some monographs have already been published. But at the same time, there are many questions remaining: What are the differences between Well-established Use and Traditional Use, and are there different interpretations from country to country? Where is the borderline between food and medicinal products? Quality and safety documentation – to what extent? How to deal with combination products – are there facilitations from recent guidelines? Can Ph. Eur. Monographs for extracts help us?

All these topics will be presented and discussed during this conference.

Target Group

This conference is of particular interest to people working in Regulatory Affairs, R&D, QA and QC of companies dealing with all categories of Herbal Medicinal Products in Europe.

Moderator

Dr Rainer Kolkmann

Programme

Potentials of Herbal Markets in Europe
- Most important markets
- Development of key molecules
- Brand success stories in Germany
- How to overcome the thread of de-reimbursement

JÜRGEN PETERSEN
IMS Health

Experiences with Marketing Authorisation and/or Traditional Registration of HMPs
- Development in Germany
- Scope of Directive 2004/24 EC
- National and European discussion
- Harmonisation?

DR WERNER KNÖSS
Federal Institute for Drugs and Medical Devices (BfArM)

Improving Public Safety by Changing from an Unregulated to Regulated Market Place
- The existing regulatory situation in the UK
- The situation which will evolve between the present day and the end of the transitional period in 2011 and beyond
- Safety issues
- Quality
- Pharmacovigilance
- User testing
- Medical information

DR DICK MIDDLETON
MH Pharma Ltd.

UK Experiences with Traditional Herbal Registrations
- UK current position
- Strategy for assisting applicants
- Experiences with registrations
- Challenges

DR LINDA ANDERSON
MHRA

Quality Requirements from a Regulator’s View
- CTD Module 3
- Although the content of module 3 of the dossier seems to be identical for all applications some specific aspects exist for herbal medicinal products
- What is absolutely necessary?
- Where may be exceptions for herbals?
- Frequent reasons for a list of questions
- Draft Guideline on Quality of Combination Herbal Medicinal Products/Traditional Herbal Medicinal Products* (EMEA/HMPC/214869/2006)

Prof REINHARD LÄNGER
Austrian Medicines and Medical Devices Agency (AGES PharmMed)
Preparing a CTD Dossier for Herbal Medicinal Products from an Industry Perspective

- Special quality issues for Herbal Medicinal Products
- Adequate tests for herbal drugs / extracts / finished products
- Method development and validation
- Stability testing
- Stability overages
- Examples from practice
- Pragmatic approach for combination products
- First experiences with Traditional Registrations under Directive 2004/24 EC in different EU member states

DR RAINER KOLKMANN
Dr. Kolkmann & Partner GmbH

Experiences with Traditional Herbal Registrations in Sweden

- The regulatory situation in Sweden
- Experiences with applications so far
- What lies ahead of us?

DR PER CLAESON
MPA

EU Regulation on Health Claims Made on Foods – Implications for Herbal Products

- Controversial classification of herbal products throughout Europe
- Borderline products are to a great extent defined by claims and the advertising given for a product
- Health claims currently used for food supplements are sometimes very close to the indications of herbal medicinal products
- Will the situation improve in the light of new European regulation on Nutrition and Health Claims made on foods?

URSULA SCHÄFER
DiapharmGruppe, Dr. Stefan Sandner GmbH

Benefits and Troubles from New Monographs in the European Pharmacopoeia

- Herbal drugs and herbal drug preparations
- Standardised, quantified, other extracts: arising problems and challenges from this classification
- Analytical and active marker
- Impact on quality control (batch release, stability testing), production, safety, efficacy and marketing/registration procedure
- Industrial perspective and practical approach

CORNELIA HÖHNE
PhytoLab GmbH & Co. KG

Suitable Reference Substances for Herbal Drugs, Extracts and HMPs

- General aspects and regulatory requirements
- How to find and select analytical markers and reference substances
- Classification of reference substances (primary, secondary, absolute, working standard, pharmacopoeial, others)
- Characterisation, quality documentation and re-testing of reference substances (how pure must a reference standard be?)
- Reference substances in the Pharmacopoeias (CRS or standard extracts in Ph.Eur.?)

DR FRIEDRICH LANG
Schwabe Phytopharmaceuticals

Registration of Herbal Medicinal Products in Poland

DR P. M. MROZIKIEWICZ
Research Institute of Medicinal Plants, Poland

Proof of 30 Years Traditional Use – a Pragmatic Approach

- Although the EU Directive 2001/83 is the legal basis for the registration of traditional herbal medicinal products there are some differences in the approach to this topic between the EU member states
- Austria is trying to find a pragmatic position between following the directive on the one hand and keeping the requirements for the applicants to a moderate extent on the other hand
- Austria’s registrations and the main points of discussion

Prof REINHARD LANGER
Austrian Medicines and Medical Devices Agency (AGES PharmMed)

Registration of Herbal Medicinal Products in France

- Regulatory situation in France with traditional herbal registration
- Harmonisation?
- The reevaluation process in the transitional period
- The food supplement position

DR GAUTHIER CARON
Merck Consumer Health Care, France
Speakers

DR LINDA ANDERSON
MHRA, London, UK
Dr Anderson joined MHRA (formerly MCA) in 1987. Within MHRA, she is a Pharmaceutical Assessor and is mainly involved with licensing applications and has specific responsibility for herbal products. Dr Anderson is Principal Assessor to the MHRA Herbal Medicines Advisory Committee (HMAC). She is UK delegate to the European Committee on Human Medicinal Products (CHMP) Quality Working Party and member of the Herbal Medicinal Product Committee (HMPC) since 2004.

DR GAUTHIER CARON
Merck Consumer Health Care, France
Dr Caron is the Director of the Regulatory Affairs and Quality Assurance Department of Merck Consumer Health Care in France. He is the deputy of Merck for the Regulatory Affairs Commission in the AESGP and the Chairman of the herbal Drug Committee in the AFIPA (French Association of the OTC Pharmaceutical Company). He joined Merck Group in 2004. Before, he worked 10 years for Schering AG. He’s pharmacist with post graduate in European regulation of drugs.

DR PER CLAESON
Medical Products Agency, Uppsala, Sweden
Dr Claeson joined the Medical Products Agency, Uppsala, Sweden, in 2001 as an assessor of efficacy and safety of herbal medicinal products. In 2006 he was appointed senior expert at the Agency. He represented Sweden in the EMEA working party for herbal medicinal products during 2001-2004 and he is currently delegate for Sweden to the EMEA Herbal Medicinal Products Committee (HMPC).

CORNELIA HÖHNE
PhytoLab GmbH & Co. KG, Vestenbergsgreuth, Germany
Cornelia Höhne studied Biology at the University of Würzburg and started her career in the pharmaceutical industry at Martin Bauer GmbH & Co. KG in 1991, during 1993 - 2006 at PhytoLab in charge of regulatory affairs, stability testing and documentation of reference substances, since August 2006 member of the Management Board and responsible for “Analytics and Quality Control” at PhytoLab.

PD DR WERNER KNÖSS
Federal Institute for Drugs and Medical Devices, Bonn, Germany
Dr Knöss is Head of Department “Licensing 5”; Complementary and Alternative Medicines and Traditional Medicinal Products at the Federal Institute for Drugs and Medical Devices (BfArM). He is German Delegate to the HMPC (EMEA, London) since July 2006. In addition, he is teaching in Pharmaceutical Biology at the University of Bonn.

DR RAINER KOLKMANN
Dr. Kolkmann & Partner GmbH, Oldenburg, Germany
Rainer Kolkmann was Head of the quality control Department of PLANTA-SUBTIL Co., Oldenburg (Germany) from 1988 to 1995, responsible for drug registration, quality dossiers and pharmaceutical expert reports. Since 1995 he is Managing director of Dr. Kolkmann & Partner GmbH, Herbal Medicinal Products – Concepts and Registrations.

PROF DR REINHARD LÄNGER
Austrian Medicines and Medical Devices Agency, Vienna, Austria
Reinhard Länger studied Pharmacy at the University of Vienna, 1982-2006 research at the Dept. of Pharmacognosy, habilitation in pharmacognosy. Since 2006 assessor in the Austrian Medicines and Medical Devices Agency in the department for herbal medicinal products and homeopathics.

DR FRIEDRICH LANG
SCHWABE Phytopharmaceuticals, Karlsruhe, Germany
Dr Lang is Head of the Analytical Development Department of SCHWABE since 1980. His scope of work covers analytical development, stability studies of HMPS, their bioanalytical and pharmacokinetical problems and general questions concerning quality of phytopharmaceuticals and their registration. He is a Qualified Person in the field of HMP-Clinical Samples.

DR P. M. MROZIKIEWICZ
Research Institute of Medicinal Plants, Poznan, Poland

Dr Middleton is a registered UK pharmacist and past-Chairman of the British Herbal Medicine Association who has worked in cancer research, retail pharmacy and in the herbal industry.

JÜRGEN PETERSEN
IMS Health, Frankfurt, Germany
Jürgen Petersen is Director Consumer Health at IMS Health, Germany. 15 years sales- and marketing functions for consumer goods/cosmetics and OTC brands with Whitehall-Much, Goededeck, and Merckle/Ratiopharm.

URSULA SCHÄFER
DiapharmGruppe, Dr. Stefan Sandner GmbH, Münster, Germany
Biologist Ursula Schäfer has been working with the Diapharm-Gruppe for more than 15 years to date. She first started her scientific career as an assistant in arteriosclerosis research at the University of Münster, before changing to the Diapharm-Gruppe. Here, her focal point is the regulatory framework for health care products such as herbal medicines, food supplements and cosmetics.

Social Event

You are cordially invited to a social event on Tuesday evening. This is an excellent opportunity to share your experiences with colleagues from other companies. We are looking forward to welcome all participants and speakers to a nice evening in a relaxed atmosphere after the first conference day.
About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit:
During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years - free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG.

More information about ECA can be obtained on the Website http://www.gmp-compliance.org

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- Certified Validation Manager (ECA)
- Certified Quality Assurance Manager - Pharmaceutical Production (ECA)
- Certified Quality Assurance Manager - API Production (ECA)
- Certified Quality Control Manager (ECA)
- Certified Pharmaceutical Engineering Manager (ECA)
- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates.
Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.
**Reservation Form (Please complete in full)**

**Herbal Medicinal Products in Europe - Harmonisation Achieved?**

13 - 14 November 2007, Berlin, Germany

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| Accommodation | CONCEPT has reserved a limited number of rooms in the Steigenberger Hotel Berlin. Reservation should be made directly with the hotel not later than 12 October 2007. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention ECA/CONCEPT to receive the specially negotiated rate for the duration of your stay. Early reservation is recommended. |

| Registration  | Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org. |

| Conference language | The official conference language will be English. |

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