EUFEPS

NEWS Letter

European Federation for Pharmaceutical Sciences March 1999 Vol 8 No 1

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Editor

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Lay-out

Liza Peterzon

Welcome to Jerusalem

On April 25, 1999, the 7th European Congress of Biopharmaceutics and Pharmacokinetics (ECBP) and the 5th Congress of the European Federation of Pharmaceutical Sciences (EUFEPS) will open in Jerusalem. At this important and timely Congress, scientists are brought together by two established European organisations dedicated to advance the pharmaceutical sciences.

The central theme of the Congress – Mechanistically Based Drug Design and Development: Integrating the Biological Revolution – recognises the profound effect that the biological revolution is having. It is moving away from empiricism to an understanding of the molecular mechanisms involved in drug action, drug absorption, drug delivery and drug metabolism, which can then be exploited to improve drug design, drug development, and ultimately the use of medicines.

Exellent programme

Plenary Lectures will cover topics such as Cellular Transporters, Receptors as Targets for New Drug Design, the Impact of Genomics on Pharmaceutical R&D, and Pharmacokinetic Strategies in Support of Mechanistically-Based Drug Discovery.

Symposia, with the participation of outstanding speakers, will cover the following topics: Designing Receptor Ligands with Better Biopharmaceutical and Pharmacokinetic Properties, Biological Pathways to Improve Drug Delivery, Biopharmaceutical Classification and Regulations, Predicting and Exploiting Pharmacokinetic Behaviour from in vitro Preclinical Data, Achieving Therapeutic Gains through Selective Targeting and Pharmaceutical Intervention in Modulation of Biological Redox Phenomena. Additionally, there will be invited speaker sessions, poster sessions and a full social programme to enable participants to renew old friendships and to make new friends.

Unique venue

Jerusalem, the Congress venue, offers participants the opportunity to enjoy a unique City – the spiritual centre of three great religions, where ancient biblical and historical sites blend with the modern amenities of the 20th century.

Visit and register!

For additional information, contact ECBP & EUFEPS Congress, P.O. Box 50006, Tel Aviv 61500, Israel. Tel +972 3 5140000. Fax + 972 3 5140077. Email ecbp.eufeps99.kenes.com Or, visit the Congress Website at: http://www.kenes.com/ecbp.eufeps99/ (also linked to PharmWeb), and register as soon as possible. We look forward to welcoming you in Jerusalem in April 1999. ■

Meir Bialer, Chair Organising Committee
Malcolm Rowland, Chair Scientific Programme Committee

April 30, 1999, is the deadline for announcements and manuscripts for the next issue of the EUFEPS Newsletter

BIOVAL '99

Regulatory Guidelines for Validation of Bioanalytical Procedures

June 21-22 • 1999 • London • UK

This major European Conference will focus on the key issues for bioanalytical validation in light of the FDA proposals put out for consultation in January 1999. BIOVAL '99 will be the first major international review of these issues since the pivotal Washington Conference on Bioanalysis in 1992.

Aim & Venue & Programme

Our aim is to develop a *European consensus view* on the key issues as part of the international debate. BIOVAL '99 will be co-hosted by EUFEPS with the *Joint Pharmaceutical Analysis Group* and the *Pharmaceutical Sciences Group* of the Royal Pharmaceutical Society of Great Britain in their London headquarters. The format is based on two half-day Sessions, plus an evening session followed by a Welcome Reception.

Leading speakers from European Regulatory Authorities, European industry and also from North America will summarise the major areas of debate – and chair parallel Workshop Sessions focusing closely on specifics. All Syndicated Workshops will be open to every delegate on a pre-selection basis, covering the following key themes and topics:

Batch Acceptance Criteria

Should QC standards be used for acceptance of calibration curves (cf FDA Guidance)?
- The 4:6:20 rule – Do we need tighter criteria or alternative criteria?

Limit of Quantitation

Alternative definitions and calculations Interpolation issues between LOD and LLOQ for use in PK studies

Standard Curves

Choosing the model – simple to complex; or "one size fits all". Determining the appropriate weighting. Number and distribution of concentration levels? Acceptance criteria for calibration points – empirical or mathematical? Identification of outliers and criteria for rejection (cf Barr Report).

Ligand Assays

Should QC standards be used for acceptance of calibration? Should Acceptance Criteria be wider than for chromatographic assays (cf FDA Guidance)?

Specific Issues for LC-MS

Determining matrix effects and defining acceptance criteria. Issues with variability of response factors – will acceptance criteria help?

Stability Issues

How can an "unstable system" be defined and quantified? Metabolites and stability problems in real samples – problems and solutions.

Sponsorship for the Conference Programme from the Covance Institute, UK, is gratefully acknowledged.

Additional Information

For Final Programme, see Second Circular available in April 1999. Also, check our website at http://www.pharmweb.net/conference/bioval99.html *or* contact Dr John Clements at RPSGB, 11 Lambeth High Street, London SE1 7JN. Tel +44 171 8203287. Fax +44 171 5820397. Email jclements@rpsgb.org.uk ■

Howard Hill, Chair JPAG
Tony Fell, Chair EUFEPS CCC

EXECUTIVE SUMMARY

February 1999

EUFEPS' seventh year of operation closed with the 5th EUFEPS Conference: "Optimising Drug Development: Fast Tracking into Human", one of the more successful events in the history of the organisation (see pages 4-5). In conjunction with this meeting, the Executive Committee met on December 6, 1998, in a wintry and nippy Wiesbaden, tuned in for Christmas.

Like many organisations, it is critical for EUFEPS to organise and run meetings. Questions which arise though are: How do we advertise meetings? Are we targeting the right people? Is our regular membership a core group for most of our meetings? Are there important individuals outside our present membership who became aware of EUFEPS through our meetings? What are the key issues to focus on? These important questions need to be addressed, if we are to run highly successful meetings, both in participation and financially.

German initiatives

In a letter to the Executive Committee Prof. Ammon (President of the German Pharmaceutical Society) proposed the establishment of a truly European Students' Meeting, to be run in Frankfurt at the end of February each year, starting in the year 2000. The event will be under the umbrella of EUFEPS and with English as the official language.

In addition, Prof. Ammon also declared that the German Pharmaceutical Society has decided to provide grants to allow up to 10 German students to participate in the European Congresses of Pharmaceutical Sciences, organised by EUFEPS every second year. The Executive Committee is delighted with this development, and hope that this example will be followed by initiatives from other Member Societies.

Substantial increase

Although the ambitious vision of 1000 Individual Members by the end of 1998 did not materialise, by January 31, 1999, membership had reached around 500, well up on the 1997 figure. Nominations for election of the Individual Membership representation at Council are now in progress.

Additional success

A notable success! EUFEPS is now recognised by EMEA as one of the European Expert Societies and the organisation has received its first EU guideline – Note for Guidance on the Investigation of Bioavailability and Bioequivalence – for consultation.

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New scope and initiatives for the European Journal of Pharmaceutical Sciences

– Publication of the very best in the pharmaceutical sciences remains our first priority, reports Prof. Per Artursson, new Editor-in-chief of the European Journal of Pharmaceutical Sciences and his co-editors, in the first issue of the 7th volume of the Journal.

In addition to Prof. Per Artursson, the new editorial team comprises Profs. Göran Alderborn, Anders Hallberg, Mats Karlsson, Matti Alarik Lang, Hans Lennernäs, Fred Nyberg and Douglas Westerlund, all from the Faculty of Pharmacy ,Uppsala University, Sweden. The remaining three issues of Volume 7 of the Journal will be published by March 1999, while all four issues of Volume 8 will also be published in 1999.

The European Journal of Pharmaceutical Sciences was established in 1992, as the official journal of EUFEPS. Profs. Hans E. Junginger and Gerard J. Mulder at the Leiden-Amsterdam Centre for Drug Research took on the onerous responsibility to co-edit this new Journal, the first six volumes of which were published under their leadership. Now further enhancements are in progress.

Further widening of the scope and territory

Already covering a remarkably wide scope of subjects, ranging from drug discovery through drug delivery to drug development, including laboratory and clinical investigations, the Journal is in the process of consolidation and further development. Also, a new definition of the scope of the Journal has been published, and a new, expanded editorial board appointed. In doing so, the proportion of non-European editorial board members has been increased to about one-third of the total number, to emphasise that scientists from all over the world are welcome to submit high quality manuscripts for the Journal.

Additional initiatives

You may have noticed already the scientific commentary, published in December 1998, the aim of which is to discuss important scientific developments and to address scientific policy issues and international initiatives. There will also be mini-reviews, providing summaries of the most recent achievements in a particular scientific field, or presenting the state-of-the-art of evolving technologies. The intention is that at least one commentary and/or one mini-review be published in each issue of the Journal. A prize for best publication in the Journal is also to be implemented.

The publisher, Elsevier, will increase promotion of the Journal, as well as provide new database software for the editors. The Faculty of Pharmacy at the Uppsala University is also upgrading its computer capability and other equipment to facilitate the editorial process.

Impact factor and publication time

The impact factor of the Journal for 1996 (published in November, 1997) was 0.991, based on citations of articles published in the 1994 and 1995 volumes of the Journal. One year later, the impact factor had substantially increased to 1.48, and it is rated a "high quality journal" by the reviewers at the Medline database. Consequently, we are pleased to report that the European Journal of Pharmaceutical Sciences has now been incorporated into this important database.

For a reputable journal, timely publication is essential. The time from the initial receipt of a manuscript to completion of the first evaluation will be reduced. So will the time from acceptance of a manuscript to its actual publication, including increased frequency of issues and production time for each issue. In 1998, the number of manuscripts for the Journal increased by 30% compared with 1997.

EUFEPS Pages

The contract, signed by officials of Elsevier and EUFEPS in October 1992, allows EUFEPS the option of an average of two pages of its own materials per issue. Announcements and advertisements of e.g. EUFEPS congresses and conferences can not wait too long to be published, and for this and other reasons, it has not been possible to regularly utilise this option. This is also true for "hot" reports on e.g. the European Commission 5th Framework Programme for Research and Technological Development (1998-2002). Currently, special procedures are being considered and developed for these pages, which will make it possible to include EUFEPS announcements and brief reports at very short notice.

Great satisfaction

The leadership of EUFEPS is very pleased with the initiatives taken by the editors, by the publisher, and by all the authors who have been, and will be, submitting quality articles to the European Journal of Pharmaceutical Sciences. Readers can rest assured, that every effort is being made to ensure that the Journal becomes a leading avenue to better medicines, through high quality publications in the pharmacuetical siences. ■

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Recommendations to be considered

The deliberations of the Working Party on Council, chaired by Prof. D. Duchêne is progressing according to plan, with the intent that its recommendations be considered by the Executive Committee.

Finance

The prognosis for 1998 indicates that the net income for the year will end up with a significant loss, estimated to about ECU 10 000. On the income side, contributions especially from congresses will come out less than budgeted. On the expense side, costs for postage and shipping are way above budget. We will look into which costs could be reduced in 1999. The number of issues published of the Newsletter could e.g. be reduced to three.

However, because of its importance, some of our reserves will be used to launch a EUFEPS' website as soon as possible.

Secretarial support

The Secretariat is now fully installed at its new facilities in Stockholm. In addition to the part-time services supplied by Anita Ljung, a half-time secretary, Jenny Hagberg, started working for EUFEPS from February 1, 1999.

The Secretariat was officially opened during a small ceremony held in the evening of February 20, in conjunction with the Executive Committee Meeting in Stockholm February 19-20, 1999. ■

Björn Lindeke
Secretary-General & Treasurer

Conference Report

5th EUFEPS Conference

Optimising Drug Development: Fast Tracking into Human

Photo: FOTO-THEIS

This unique discussion forum for scientists from the pharmaceutical industry, regulatory agencies and academic institution, which took place on December 7-9, 1998, at Kurhaus in Wiesbaden, Germany attracted more than 200 delegates. The aim of the Conference, to review the current practice in and around early human drug development, and to explore how modern scientific technological developments could and do further improve this practice, was well fulfilled. The Conference, organised by EUFEPS, was co-sponsored by European Association of Clinical Pharmacology & Therapeutics (EACPT), the European Medicines Evaluation Agency (EMEA), US Food and Drug Administration (FDA), and the American Association of Pharmaceutical Scientists (AAPS).

Roeline Jochensen

EUFEPS President, Prof. Malcolm Rowland, in opening the Conference, emphasised that the pressures on accelerating and optimising drug discovery and development are ever increasing. And, that the focus of the Conference dealt with one particular component, namely the early phase of human drug development. The opening address was then followed by a forthright and challenging introductory lecture by Dr Carl Peck, entitled "From discovery to market in less than five years: Intensifying the front end of drug development".

Conference format, topics and report

The two and a half day programme was divided into seven sessions, the seventh one used to develop conference conclusions and recommendations. The sessions preceding the final discussion were: Prediction and rapid human screening of pharmacokinetic properties; Prediction and rapid human screening of biopharmaceutical formulation properties; Preclinical data to facilitate rapid entry into human; Rapid assessment of proof of concept; Clinical pharmacology: Fast tracking in specific therapeutic areas; and New technologies accelerating human drug development. In these sessions, thirty invited speakers, and a number of submitted posters, discussed the issues involved. In addition, a small exhibition created many opportunities for additional interactions on the various topics during the coffee and lunch breaks.

There were many excellent presentations followed by subsequent discussions after each session, which formed the material for the respective small evening working parties. These small groups were tasked with bringing forward recommendations at the final session of the Conference, and in particular what still needs to be addressed, to facilitate fast tracking into human during drug development.

Photo: FOTO-THEIS

The conclusions and recommendations that emerged from this Conference will form part of a co-joint consensus document, for wide circulation and discussion, incorporating the outcome of a tandem conference which took place in Washington, DC, USA, September 1998.

Better informatic systems needed

A common plea, emerging from many of the sessions, was the need for much better informatic systems and mechanistically-based models, coupled with simulation. Such systems are needed not only to capture and organise the vast volume of data coming out of the drug discovery and preclinical programmes, but also to integrate this information to facilitate quantitative prediction of likely events in human, as well as improve the clinical evaluation and development of new, and often novel, therapeutic agents.

It was also recognised that new technologies presented in the penultimate session of the meeting, such as non-invasive imaging techniques for in vivo studies, accelerated mass spectrometry and advances in proteomics and genomics, are opening up many possibilities to address existing problems and bottlenecks. Many additional points also emerged from each of the sessions.

Predicting pharmacokinetics

While much progress had been made in recent years in predicting pharmacokinetics from in vitro and preclinical data, with fewer of the

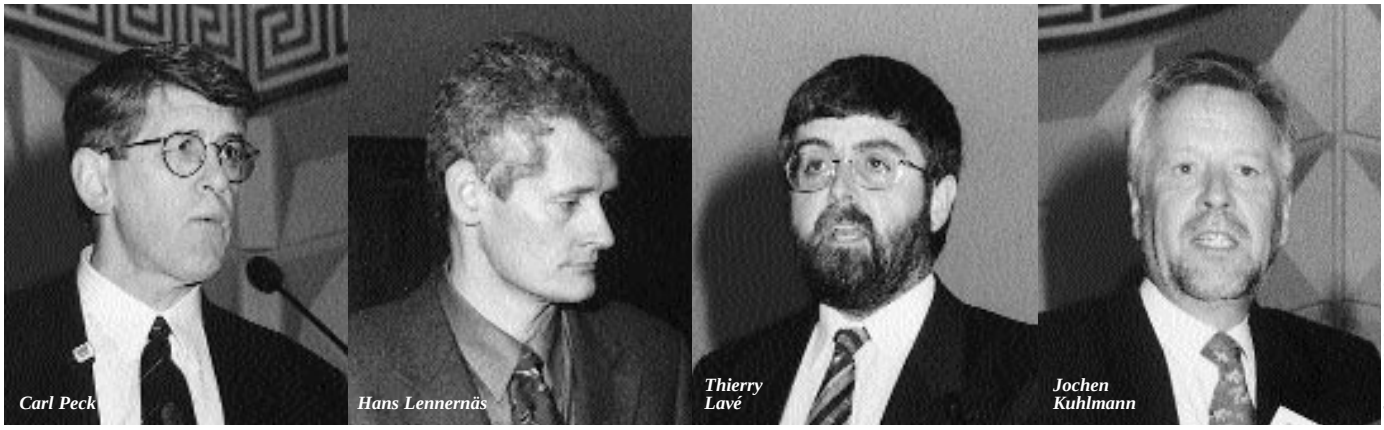

Photo: FOTO-THEIS

compounds entering man subsequently rejected on grounds of poor pharmacokinetic properties, several areas still needed improvement including: Better and validated human in vitro systems, such as hepatocytes; coupling of the pharmacokinetics with preclinical pharmacodynamic data, to facilitate compound selection and help define the desired concentration-time profile in humans, and; better understanding of structure-pharmacokinetic relationships to help guide the medicinal chemist in drug design. A proposal to use cassette dosing, increasing popular in animal studies, in humans during Phase 1 raised many issues which would need to be resolved if this procedure was to be implemented.

Challenges in biopharmaceutics

Many outstanding challenges in the biopharmaceutical arena exist, spurred on by an ever increasing pressure to have at the earliest stage of Phase 1 testing, not only compounds with good absorption profiles, but also fabricated as the formulation most likely to be used clinically. Particularly stressed was the need for better computational methods to rapidly and reliably predict physical and physiochemical properties, such as solubility and permeability, as well as the maximum possible dose absorbed, relevant when considering the likely effective dose needed.

Needs for preclinical safety

Preclinical safety assessment is undergoing significant changes driven on by advances in molecular biology. And, while cellular systems are increasingly used, it was recommended that animal models should not be abandoned, for example in teratology. Also, the request for better predictive, reliable and validated biomarkers (surrogates) of safety, was echoed and broadened by the group dealing with rapid assessment of proof of concept (efficacy) in humans. This group also pushed for an increased use of intelligent adaptive and informative designs to compress clinical trials, better tools to account for inter-subject variability, as well as proposing the use of challenge/provocation tests to establish transient disease models under controlled laboratory conditions.

Clinical focus

The clinical session focussed on specific issues needed to accelerate assessment for endocrine dysfunction/osteoporosis, oncology and neurodegeneratives. The need for validated surrogate markers/endpoints was emphasised in order to rationalise the proof-of-concept approach. PK/PD guided designs in clinical pharmacology studies was also advocated, especially in oncology. In addition, revision of regulatory guidelines was emphasised as an important measure to accelerate the development process.

Successful interactions

All in all, the meeting was a great success, bringing together experimental and clinical scientists, statisticians and physicians to meet the challenge of optimising and accelerating drug development.

■

Hans H. Lindén
Malcolm Rowland

Photo: FOTO-THEIS

Honorary Membership

Prof. Malcolm Rowland, President of EUFEPS, has been awarded Honorary Membership by the Royal College of Physicians in UK for contributions in the area of research and teaching in pharmacokinetics to the development and use of medicines.

The Royal College of Physicians is the oldest medical institution in England, receiving its Royal Charter granted by Henry VIII in 1518. Honorary Membership is conferred on those who have made outstanding contributions to medical sciences, but who do not hold a medical degree. The formal award ceremony took place on December 16, 1998, at the college premises in Regents Park, London, UK ■

Current EMEA Information

The European Agency for the Evaluation of Medicinal Products

November 1998 – January 1999

- C· CPMP/BWP/2833/98 Workplan for the CPMP Biotechnology Working Group Party 1999-2000 Status 1999
- CPMP/EWP/556/95 – Points to consider on Clinical Investigation of Slow-Acting Anti Rheumatic Medicinal Products in Rheumatoid Arthritis
- CPMP/EWP/563/95 – Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Parkinson's Disease
- CPMP/EWP/2963/98 – Workplan for the CPMP Efficacy Working Party 1998/99 – Status December 1998
- CPMP/EWP/QWP/1401/98 Draft – Note for Guidance on the Investigation of Bioavailability and Bioequivalence
- CPMP/EWP/23895 Rev. 1 – Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension
- CPMP/2457/1998 Press Release – Recommendation for the Suspension of the Marketing Authorisation for Tasmar–EU/1/97/044/001- 006
- CPMP/EWP/518/97 Concept Paper on the Revision of the Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Medicinal Products for the Treatment of Depression
- CPMP/EWP/559/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Product (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Osteoporosis in Men
- CPMP/EWP/560/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Points to Consider on Clinical Investigation of Medicinal Products for the Treatment of Acute Ischemic Stroke
- CPMP/EWP/561/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Multiple Sclerosis
- CPMP/EWP/563/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for Treatment of Venous Thromboembolic Disease
- CPMP/EWP/566/98 Concept Paper on the Revision of the Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Epileptic Disorders
- CPMP/EWP/567/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for Bipolar Disorders
- CPMP/EWP/570/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Points to Consider on Clinical Investigation of Medicinal Products for the Treatment of Unstable Coronary Artery Disease
- CPMP/EWP/571/98 Concept Paper on the Revision of a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Cardiac Failure
- CPMP/EWP/707/98 Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for Prophylaxis of Intra- and Post-Operative Venous Thromboembolic Risk
- CPMP/EWP/714/98 Concept Paper on the Revision of the Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Clinical Investigation of Medicinal Products for Peripheral Arterial Occlusive Disease (PAOD)
- CPMP/ICH/300/95 –Note for Guidance on Duration of Chronic Toxicity Testing in Animals (Rodent and Non-Rodent Toxicity Testing)
- CPMP/PhVWP/2607/98 – Workplan for the CPMP Pharmacovigilance Working Party 1999, Status December 1998.
- CPMP/QWP/2430/98 – Concept Paper on the Revision of the Note for Guidance "European Drug Master File Procedure for Active Substances"
- CPMP/QWP/2431/98 – Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on Parametric Release
- CPMP/QWP/2809/98 – Concept Paper on the Revision of Note for Guidance on Radiopharmaceuticals
- CPMP/SWP/799/95 Rev 4 Non-clinical testing of substances with long-term marketing experience(old substances)
- CPMP/SWP/160/98 Concept Paper on Immunotoxicity
- CPMP/SWP/2623/98 – Workplan for the CPMP Safety Working Party 1999 – Status December 1998
- CPMP/WQP/2570/98 – Concept Paper on the Development of a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance on "In-Use-Stability Testing of Non-Sterile Human Medicinal Products
- Catalogue of EMEA Public Documents January 1999
- EMEA/39260/1998 – Tasmar – Suspension of the Marketing Authorisation
- EMEA/39582/1998 – Press Release Entacapone – Update of Product Information
- EMEA/40211/1998 – Report on EFPIA Info Day Nov. 20, 1998
- EMEA/40532/1998 – Press Release Mabthera – Reports of adverse reactions – New recommendations for use
- EMEA/42941/1998 – EMEA response to ISDB assessment of 9 EPARs
- EMEA/42968/98 – Procedure on the granting of Marketing Authorisation by Central and Eastern European Countries for Medicinal Products for Human use authorised in the European Union following the centralised procedure and the variation and renewal of such Marketing Authorisations
- EMEA/42968/1998 Rev. 1 Procedure on the Granting of Marketing Authorisation by Central and Eastern European Countries
- EMEA/823/1999 Summary of the Joint EMEA/EFPIA Survey on the Centralised Procedure 1998
- EMEA/2877/1999 Report on EMEA – AESGP Information Day 28 January 199
- EMEA/H/30313/1998 – Procedure for Notification of Parallel Distribution of Centrally Authorised Medicinal Products
- EMEA/H/38179/1998 – Pre-Submission Guidance for users of the Centralised Procedure
- EMEA/H/RB/40109/98 – Report on Interested party meeting, Nov. 19, 1998
- EMEA/HMPWG/20/99 Draft Comments on the Commission Regulation (EC) No 541/95 of 10 March 1995 Concerning the Examination of Variations to the Terms of a Marketing Authorisation Granted by a Competent Authority of a Member State as amended by Commission Regulation (EC) No 1146/98
- EMEA/HMPWG/22/99 Draft Comments on the European Commission Guideline on dossier requirements for Type I variations Notice to Applicants Vol. 2 A
- EMEA/HMPWG/17/99 Draft Comments on the Draft Directive on Good Manufacturing Practice (GMP)
- EMEA/HMPWG/18/99 Draft Comments on the Document Good Agricultural Practice (GAP) from the European Herbs Growers and Producers Association of 5 August 1998
- EMEA/HMPWG/19/99 Draft Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drug Preparations (Herbal Drugs) and Herbal Medicinal Products
- EMEA/HMPWG/21/99 Draft Comments on the CPMP Note for guidance on Stability Testing after a Type II Variation to a Marketing Authorisation
- EMEA/HMPWG/23/99 Draft Points to Consider on the Evidence of Safety and Efficacy Required for Well-established

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Promoting research activities within the European Community

The European Union (EU) is promoting research activities covering almost all advanced areas of technology. The strategic objectives of the research programmes are to link the ability to discover with the ability to produce, in order to address the needs of society and to meet the requirements of the consumer, thus leading to future wealth and strengthening the competitiveness of the European industry, and creating new jobs in Europe.

Framework programme

The main research activities in the EU are organised within framework programmes. The First Framework Programme was established in 1984. The Fourth Framework Programme was closed at the end of 1998. A proposal for The Fifth Framework Programme for Research and Technological Development (FP5) has been launched by the EU Commission, and this programme has been progressing by negotiation between member states of the EU during the last year. The European Commission and the EU Parliament have suggested a total budget of 16,300 million euro, although the member states would like to spend only 14,000 million euro on the programme. In November 1998, an agreement on the total budget was settled between the Council and the Parliament and the proposed budget will be 14,960 million euro for the years 1998-2002. A final agreement between the Council (member states) and the Parliament including all details, was finalised by the end of 1998. Thereafter the programme will be open for calls during the time period 1999-2002.

Thematic and horizontal programmes

FP5 has a new structure compared to the previous programmes. It is based on four thematic programmes and three horizontal programmes. In the Fourth Framework Programme the number of themes were eighteen. FP5 is more focused and integrates different research areas. They are: Quality of life and management of living resources; User-friendly information society; Competitive and sustainable growth; Energy, environment and sustainable development. The horizontal programmes are: Confirming the international role of Community research; Promotion of innovation and encouragement of participation of SMEs (small and medium size enterprises); Improving human research potential and the socio-economic knowledge base.

Frame and specifics

These constitute the frame, supplemented by "specific programmes" at a more detailed Programme level. In a third level of information are the working programmes and the information packages. Draft versions of these are just now in the consultation process by the programme committees (representatives from the member states). From the point of view of the pharmaceutical sciences, the first thematic programme on Quality of life and management of living resources is of most interest, covering areas such as: health, food and environmental factors; control of infectious diseases; the cell factory; the ageing population; and support for research infrastructures.

Another interesting programme is entitled: Improving human research potential. This programme will include a number of grants for training and mobility of researchers.

Networks needed

All framework research projects are built on networks with participants from different research groups/centres in the EU. For scientists interested in participating in FP5, it would be timely to establish these networks for tentative research project/s in the immediate future. Research co-operation between academia and industry is highly supported. In FP5 it will also be possible to co-operate with research groups in the USA, Israel, South Africa and Eastern Europe, in addition to research groups in Norway, Iceland and Switzerland.

Additional information and contacts

For detailed information, please consult the following homepages on the Internet, continuously updated, and also available for downloading documents:http://europa.eu.int/comm/dgl2/fp5.html *and* http://www.cordis.lu/fp5/home.html

The first call for proposals of research projects in FP5 has already been launched within the research area of Information Technology. For the Life Sciences programme a proposed date for the first call for proposals will be March 2, 1999 with submission dates of June 1, 8 or 15, depending on key action.

For strategic information on developing a strong position for submitting a proposal under FP5, those interested are advised to contact their national (or local) representatives with direct contacts in the Brussels system.

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Maj-Inger Nilsson
EUFEPS EU Liaison Officer

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Herbal Medicinal Products in Bibliographic Applications

- EMEA/HMPWG/24/99 Draft Proposal for a core SPC for Ispaghula husk
- EMEA/HMPWG/16/99 Final comments for Revision of the Notice to Applicants Volume 2B Part ICI Tabular Formats Specific to Herbal Medicinal Products
- EMEA/HMPWG/8/99 Final Comments for Revision of the Notice to Applicants Volume 2 B Part II Concerning Chemical, Pharmaceutical and Biological Documentation for Vegetable Medicinal Products
- EMEA/HMPWG/15/99 Note for Guidance on Fixed Combinations of Herbal Medicinal Products with Long-Term Marketing Experience – Guidance to Facilitate Mutual Recognition and Use of Bibliographic Data
  EMEA/MB/011/98 Rev. 2 Points to consider for an EMEA communication policy
- EPARs

CPMP/259/98	Mabthera
CPMP/584/96	Invirase
CPMP/589/96	Crixivan
CPMP/590/97	Mirapexin
CPMP/591/97	Sifrol
CPMP/767/95	Cellcept
CPMP/896/96	Insuman
CPMP/1249/98	Comtess
CPMP/1986/98	Micardis
CPMP/1987/98	Pritor
CPMP/1988/98	Telmisartan
CPMP/2178/98	Comtan
CPMP/2590/98	Prometax

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Validation of Solid Dose Pharmaceutical Products
May 17-19, 1999, Cobham, UK
Contact: Dr J A Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, U.K.
Fax +44 171 5820387
Email jclements@rpsgb.org.uk

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Symposium: The Control of Fermentation Processes
May 20, 1999, London, UK
Contact: Dr J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 0171 5820397
Email jclements@rpsgb.org.uk

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6th Intermediate Level Workshop on Pharmacokinetic/Pharmacodynamic Data Analysis: A Hands-on Course Using WinNonlin
June 7-10, 1999, Cambridge, U.K.
Contact: Dr J A Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street London SE1 7JN, U.K.
Fax +44 171 5820387
Email jclements@rpsgb.org.uk

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BIOVAL '99 Regulatory Guidelines for Validation of Bioanalytical Procedures
June 21-22, 1999, London, UK
Contact: Dr J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 0171 5820397
Email jclements@rpsgb.org.uk

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Symposium: Intravenous Pharmaceuticals – Stability in Practice
June 24, 1999, London, UK
Contact: Dr J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 0171 5820397
Email jclements@rpsgb.org.uk

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Advanced Course in Analytical Validation and Regulatory Issues
June 30 – July 2, 1999, York, UK
Contact: Dr J A Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820387
Email jclements@rpsgb.org.uk

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Basic Pharmacokinetics: A One Week Workshop
July 11-16, 1999, Arosa, Switzerland
Contact: Irene Sung, School of Pharmacy, University of Manchester, Manchester M13 9PL UK, Fax +44 161 2738196
Email Isung@fs1.pa.man.ac.uk

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2000 Years of Natural Products Research – Past, Present and Future. Joint Meeting of the ASP, AFERP, GA and PSE
July 26-30, 1999, Amsterdam, The Netherlands
Contact: Congress 1999, Div. of Pharmacognosy, LaCDR, P.O. Box 9502, NL-2300 RA Leiden, The Netherlands, Fax +31 71 5274511
Email fcogsymp@lacdr.leidenuniv.nl

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7th European ISSX Meeting
August 22-26, 1999, Budapest, Hungary
Contact: 7th European ISSX Meeting, Mrs Klára Láng & Mr Attila Varga, Diamond Congress Ltd, Fö u. 68, H-1027 Budapest, Hungary, Fax +36 1 201 6383, Email diamond.eft@mtesz.hu

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EUFEPS 2000

6th European Congress of Pharmaceutical Sciences

September 16-19 • 2000 • Budapest • Hungary

Plans are well advanced for EUFEPS 2000 hosted by Hungarian colleagues in Budapest, the heart of Central Europe.

International scientific programme

The Scientific Programme set up by the International Scientific Committee chaired by Professor Sándor Görög with Professor Ernst Mutschler will cover: Strategies and Technologies in Drug Discovery; Key Issues and Advances in PK and Drug Metabolism (to include Rapid Screening Methods, Optimising PK in Early Drug Development); Fundamental Advances in Pharmaceutical Technology; Challenges and Perspectives in Natural Product Chemistry; The Genome Era; Challenges in Analytical Chemistry; Advances in Pharmacology. A major feature of the programme will be the whole-day Symposium organised with the International Pharmaceutical Excipients Council (IPEC).

Attractive social programme

The elegant National Gallery of Art will house the Welcome Reception – with a feast to celebrate the gastronomic delicacies and fine wines of Hungary. An adventurous evening River Boat Party with dinner on the Danube will also feature in the Social Programme. A range of visits to the most famous venues in and outside the city will also be available for accompanying persons.

Training courses and satellite as well

There will also be Training Courses on a range of topics and a Satellite Symposium, BIOVAL 2000, designed to review the outcome of the consultation process initiated by the FDA with the AAPS on the proposed Guidelines for Validation of Bioanalytical Methods – a major European focus on an area with a vital regulatory impact.

Abstracts welcome

All scientists working in any area of the pharmaceutical sciences are invited to submit one or more abstracts for presentation at EUFEPS 2000. Abstract forms will be available in the Second Circular (to be distributed in mid-May, 1999).

Visit website

Further information on the programme and format for submission of abstracts for presentation can also be obtained by visiting the Website at: http://www.pharmweb.net/conference/eufeps2000.html ■

Szabolcs Nyiredy, Chair EUFEPS 2000
Tony Fell, Chair EUFEPS CCC

Workshop: Dissolution and Dissolution Testing Specifications
September 2-3, 1999, London, UK
Contact: Dr J A Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820387
Email jclements@rpsgb.org.uk

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The British Pharmaceutical Conference
September 13-16, 1999, Cardiff, U.K.
Contact: Dr J A Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, U.K.,
Fax +44 171 5820387
Email jclements@rpsgb.org.uk

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3rd Central European Symposium on Pharmaceutical Technology
September 23-24, 1999, Portoroz, Slovenia
Contact: Prof. Ales Mrhar, Faculty of Pharmacy, University of Ljubljana, Askerceva 7, SLO-1000 Ljubljana, Fax +386 61 1258031
Email ales.mrhar@ffa.uni-lj.si

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Lipid and Surfactant Dispersed Systems. Fundamentals, Design, Formulation, Production
September 26-28, 1999, Moscow, Russia
Contact: APGI, Rue Jean Baptiste Clément F-92296 Chatenay Malabry Cedex, France
Fax +33 1 46835308
Email apgi.apgi@cep.u-psud.fr

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Biologicals Beyond 2000: Challenges for Quality Standards in an Evolving Field and Satellite on Veterinary Biologicals.
September 27-29 1999, Strasbourg, France
Contact: Dr C. Le Tarnec, European Dept for the Quality of Medicines, Council of Europe, BP 907, F-67029 Strasbourg, France, Fax +33 3 88412771, Email info@mail.pheur.org

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International Symposium on Analysis of Carbohydrates
September 27-29, 1999, Stockholm, Sweden
Contact: The Analytical Section, The Swedish Chemical Society, Wallingatan 24, SE-111 24 Stockholm, Sweden, Fax +46 8 106678
Email monika@chemsoc.se

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BIO International '99 Conference
September 29 - October 1, 1999, London, UK
Contact: Prof. Kamal K. Midha, College of Pharmacy and Nutrition, University of Saskatchewan, Sask. S7N 5C9, Canada
Fax +1 306 9666354, Email metz@sask.usask.ca

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Drug Delivery for the Third Millennium
October 10-12, 1999, Pisa, Italy
Contact: Controlled Release Society Administrative Headquarters, 1020 Milwaukee Ave., Suite 335, Deerfield, IL, USA
Fax +1 847 8087073

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