EUFEPS

NEWS Letter

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Address

EUFEPS Secretariat
PO Box 1136
SE-111 81 Stockholm, Sweden
Phone +46 8 7235000
Fax +46 8 4113217
Email secretariat@eufeps.org
Website www.eufeps.org

Editor
Hans H. Lindén

Lay-out
Camilla Boquist/Lådan & Co

EDITORIAL

EUFEPS' New President:

Future Tasks for EUFEPS

It is a very heavy responsibility to become President of EUFEPS, but it is also an extremely exciting task to be faced with. As I already pointed out in my previous Editorial (March 2000 issue of this Newsletter), I am very concerned about the problem of communication, and especially communication between EUFEPS and its membership – the Member Societies and the Individual Members.

A two-dimensional matrix

To develop a better communication with its members it is necessary for EUFEPS to know them better, i.e. to know you better, and to know in what kind of activities we could collaborate within EUFEPS.

With this in mind, EUFEPS has prepared a two-dimensional matrix or network in which appear, on one side, scientific disciplines (e.g. analytical chemistry, biotechnology, drug delivery, medicinal chemistry, pharmacology, etc.), and, on the other side, R&D processes (drug design and discovery, exploratory drug development etc.). Of course, there should be a third dimension to it: pharmaceutical policies and regulatory affairs, which will be added later.

The matrix will be sent to you (Member Societies and Individual Members), asking you to indicate on it where you feel you belong, or what area concerns you most. We also ask you to provide names of individuals who could be "placed" on this matrix. Doing so will result in two major advantages for EUFEPS. Firstly, Member Societies could be identified for closer collaboration in the future, e.g. for the organisation of future European events. Secondly, it will help EUFEPS to define and establish the "European School of Excellence in Pharmaceutical Sciences", as well as to initiate and organise high-level courses and conferences.

Double scientific orientation

It is my personal feeling that, up to now, EUFEPS has probably been more concerned with the industrial aspect of pharmaceutical sciences than with the basic or academic aspect. Of course, these two aspects are not mutually exclusive, but due to the very busy life we lead, we are obliged to make choices. We cannot participate in as many conferences or events as we would like to, whatever their interest and value.

This means that, in the future, EUFEPS will have to pay as much attention to academia as to industry. In addition to the existing Committee for Industrial Relations (CIR), there will be a Committee for Academic Relations (CAR). Both committees would be in charge of proposing scientific events corresponding to the two aspects (industry and academia), either as separate events, or as joint events. To be effective, the two Committees would have to work in close collaboration, as well as with other EUFEPS committees, including the Committee on Training and Education.

What kind of meetings for EUFEPS?

In the future, there must be a clear policy as to meetings organised, co-organised, and co-sponsored by EUFEPS. A clarification of the following points is necessary:

1. Level (global; intercontinental; European international; regional within Europe; national)
2. Nature (congress; conference; symposium; short course; training programme)
3. Orientation (industrial or basic research; drug discovery, drug development etc.)
4. Dates well in advance of the meetings.

In addition, there must not be any fruitless competition or overlapping, neither in what EUFEPS is organising itself, nor what EUFEPS and its Member Societies are organising separately.

On the *global* level we plan to continue to collaborate with FIP in the organisation of the World Congress on Pharmaceutical Sciences (the first one being the Millennial World Congress, held in San Francisco, in April 2000).

The World Conference on Drug Absorption and Drug Delivery (June 18-20, 2001, in Copenhagen, Denmark) is a good example of *intercontinental* collaboration. It will be organised by EUFEPS, and it is

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Februari 1, 2001, is the deadline for announcements and manuscripts for the next issue of the EUFEPS Newsletter

WANTED

The European Federation for Pharmaceutical Sciences seeks an

EDITOR

for this highly acclaimed Newsletter, which is published quarterly (in March, June, September and December). The duties of the Newsletter Editor include:

- production of four issues (eight pages A4 each) per year
- initiating, and/or drafting, editorials or leading articles
- planning, suggesting and stimulating continuous in-flow of other articles and items
- review, complete and edit manuscripts, including with pictures
- consider the extent of available manuscripts and add necessary instructions for layout and technical production
- check and correct (scientific) terminology, as well as the English
- supervise the copy editor, providing assistance and help regarding layout and contacts with the printer

EUFEPS is seeking a highly motivated person wishing to play a key role on the "editorial team". Although a voluntary position, all technical equipment and software needs will be provided, if required, and all reasonable telecommunication costs covered. In addition, EUFEPS will provide funding to allow the Newsletter Editor to attend at least one EUFEPS meeting annually.

Whether an experienced editor, or wanting to develop or refine your skills in the field, persons interested in this important and exciting position are invited to contact the EUFEPS Secretary-General/Treasurer, Prof. Björn Lindeke, for further details, PO Box 1136, SE-111 81 Stockholm, Sweden; tel +46 8 7235061; fax +46 8 4113217; email bjorn.lindeke@swepharm.se; website www.eufeps.org

EXECUTIVE SUMMARY

December 2000

New leadership

The Executive Committee, which was elected in 1999, met in Budapest on September 16, 2000, in conjunction with the EUFEPS Council and 2000 Congress in Budapest, Hungary. Following the Council elections, the newly elected Executive Committee then met on Monday, September 18, 2000. At this meeting, Prof. D. Duchêne was elected President of EUFEPS, and Prof. O.J. Bjerrum Vice-President. For all members of the newly elected Executive Committee, including current responsibilities, see page 3.

The EUFEPS Journal

Invited to participate in the first of these Executive Committee meetings was Prof. P. Artursson, in his capacity of Editor-in-Chief for the European Journal of Pharmaceutical Sciences (EJPS). A major issue to be discussed was the upcoming situation with a change of the Editorial office, due to the fact that Prof. Artursson and associates are stepping down next April. The development of the Journal during the three last years has been excellent, but three-year rotations of the Editor-in-Chief are too short periods. We need to do whatever we can to keep and further develop the Journal, even though the contract is to be set between the Editor and the publisher, Elsevier Science, and not with EUFEPS.

New model and initiative

Other items dealt with at these meeting were the arrangements for the Council Meeting and issues related to future EUFEPS strategies. To be noted are, the Open Forum and the new model for the Representation at Council, which also comprises an adjustment of the Membership Fee structure. It was also felt that the concept about process orientation should be moved forward, as soon as possible (see Editorial page 1). Some thoughts were given on how we can get into a better dialogue with the Member Societies, which is also discussed by the new President in the Editorial.

New Safe Medicines Faster

The Report from the March 2000 Workshop on New Safe Medicines Faster (NSMF) was well received in Brussels, where the Commission currently is working on it. Thus the chances seem to have increased that something will appear in the next EU's RTD Framework Programme. Furthermore, the dissemination of information for lobbying about the initiative has started. A letter to ministries, agencies etc. to go with the document has been put together, and applicable promotional activities have begun (see pages 4-5). One is now looking for models on how to integrate NSMF with the current framework programme, including in the form of a European integrated researsch project.

New committees

To foster the development of EUFEPS working committees the Executive Committee met with Prof. J. Morais from Lisbon, who has been a member of the Committee on Pharmaceutical Policies (CPP) from its very beginning. The CPP has created ideas and initiated some good meetings, but it has become quite clear that there are logistic problems with this Committee. It was suggested that it may be wiser to focus on "regulatory affairs" for the time being. Science driven regulatory affairs will need a proper plan to play from.

With regard to the structure of and responsibility for conferences and congresses, it was agreed that Prof. H. de Jong should take over the responsibility for the activities that were previously handled by Prof. A. F. Fell.

The newly elected President, Prof. D. Duchêne, stressed the importance of setting up a better calendar concerning some of the EUFEPS' activities (see Editorial).

EUFEPS Website

The EUFEPS Website was launched in September 2000, and the contents of it was updated, recently. Posted are e.g. an extensive report on the New Safe Medicines Faster Project, as well as forthcoming EUFEPS meetings. Also, there are links to several of the EUFEPS Member Societies and liaison organisations. The Website will be further developed, and feed-back on the current one and other input will be welcome.

Next meetings

The next report will cover Executive Committee meetings to be held on November 11-12, 2000, in Basel, Switzerland, in conjunction with the 7th EUFEPS Conference on Optimising Drug Development: Strategies to Assess Drug Metabolism/Transport Interaction Potential – Towards a Consensus, and on February 24-25, 2001, in Frankfurt, Germany, in conjunction with the 3rd European Students Meeting.

Prof. Björn Lindeke
Secretary-General and Treasurer

Current Leadership of EUFEPS


Dominique Duchêne


Ole J. Bjerrum


Malcolm Rowland


Björn Lindeke


Bernd Clement


Henk de Jong


Anders Grahnén


A. Atilla Hincal


Rodolfo Paoletti


Michel Veillard

The current leadership of EUFEPS comprises ten persons. They are, including title, name, term of office, responsibility, and current affiliation:

Prof. Dominique Duchêne, President (1999-2001)
Director of the research group on "Improvement of therapeutic efficiency of active molecules by means of cyclodextrins and bioadhesion", Paris-Sud University, Paris, France.
Email dominique.duchene@cep.u-psud.fr

Prof. Ole J. Bjerrum, Vice-President (1999-2001)
Industrial Relations & New Safe Medicines Faster
Research Counsellor at Corporate Research Affairs, Health Care, Novo Nordisk A/S, Bagsvaerd, Denmark. Adjunct professor in Industrial Biomedicine, University of Southern Denmark.
Email ojb@novo.dk

Prof. Malcolm Rowland, Past-President (2000-2002)
Awards & Prizes
Professor of Pharmacy and Director of the Centre of Applied Pharmacokinetic Research, University of Manchester, UK.
Email malcolm.rowland@man.ac.uk

Prof. Björn Lindeke, Secretary-General/ Treasurer (ex-officio member)
Finance and Secretariat
Executive Director of the Swedish Pharmaceutical Society and Academy of Pharmaceutical Sciences, Stockholm, Sweden.
Email bjorn.lindeke@swepharm.se

Prof. Bernd Clement (1999-2001)
Education and Training
Professor of Pharmaceutical (Medicinal) Chemistry and Director of the Pharmaceutical Institute, Christian-Albrechts-University, Kiel, Germany.
Email bclement@pharmazie.uni-kiel.de

Prof. Henk de Jong (2000-2002)
Conferences and Symposia
Director of International Scientific Relations at Corporate R&D of Servier, Courbevoie, France.
Email dejong@netgrs.com

Dr Anders Grahnén (2000-2002)
Liaison Organisations
Vice-President and Director R&D, Quintiles AB, Uppsala, Sweden. Associate Professor in Pharmacokinetics and Biopharmaceutics, University of Uppsala, Sweden.
Email anders.grahnen@quintiles.com

Prof. A. Atilla Hincal (2000-2002)
Pharmaceutical Policies
Dean of Post-Graduate Institute of Medicine and Health Sciences and Head of the Pharmaceutical Technology Department, Hacettepe University, Ankara, Turkey.
Email hincal@tr.net

Prof. Rodolfo Paoletti (2000-2002)
Academic Relations
Professor and Chairman of Pharmacology, School of Pharmaceutical Sciences, University of Milan, Italy.
Email sisf@comm2000.it

Dr Michel Veillard (1999-2001)
Membership
World-wide Director of Pharmaceutical Sciences/ Preformulation, Aventis Pharma S.A., France.
Email michel.veillard@aventis.com

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co-sponsored by American and Japanese scientific organisations. It has been suggested that it should continue on a two year cycle, circulating around the three continents.

On the *international* scene, EUFEPS will strengthen its present Congress. The next EUFEPS Congress will be held in 2002 in Stockholm. For 2004, the intention is that the Congress be developed into a new type of event, the European Pharmaceutical Sciences Fair. This means that during one week, in the same place, a number of "congresses", "conferences", "symposia" in different fields of the pharmaceutical sciences, but still forming one big event, will take place. At the EUFEPS 2002 Congress, some of these ideas will be considered for implementation.

Also, on the *European* level, EUFEPS will organise symposia on well defined topics, oriented either towards industry or towards academia or both. This could also be done in co-operation with EUFEPS Member Societies.

On the *regional* or *national* level, EUFEPS will support events organised by its Member Societies, with the aim of spreading and strengthening scientific pharmaceutical knowledge all over Europe. EUFEPS will also organise and support student meetings.

In closing

These are just a few ideas that I have, at the beginning of my Presidency. I hope that you will come up with many new activities for EUFEPS. Anyway, I shall keep you informed of any new EUFEPS project.

Dominique Duchêne, Professor, EUFEPS President

Health and Wealth in the EU

How to improve the conditions for research and faster development of new safe medicines in Europe?

In this article, Prof. Ole J. Bjerrum discusses how to improve the current situation, based on the today's outcome of the EUFEPS New Safe Medicines Faster initiative (NSMF). This initiative was taken, approx. one and a half years ago, and the ultimate goal of it is to contribute to effective development of medicines for the benefit of the European citizens. For the initial Position Paper (August 1999) and the outcome of the Project Workshop (March 2000), as well as for other information on the Project, including this article, consult and refer to the EUFEPS Webiste: www.eufeps.org

Introduction

Traditionally, pharmaceutical companies, headquartered in Europe, have played a leading role in developing new medicines globally. The current trend indicates that American companies have overtaken this position. A major reason is the dedication of the American government to provide a very strong platform in basic research and advanced technology that stimulates pioneering science and entrepreneurship. In this dynamic environment, American companies have been quicker to adopt new technologies for the production of new medicines, further favoured by an open dialogue with their regulatory authorities. Since the pharmaceutical industry contributes significantly to the generation of value and jobs in Europe, this detrimental trend must be reversed.

Urgent needs

To strengthen the European competitiveness in innovation and use of new and better medicines, the European Commission needs to make a dedicated effort to support research and training in pharmaceutical and related sciences, including disciplines of importance to the health authorities. Furthermore, the research underpinning the development of new medicines is so comprehensive regarding advancement, diversity and dynamics that this alone also qualifies the topic to be a major research locomotive in the coming EU framework programme for research, technology and development. Besides, it involves a multitude of research disciplines, while the process itself gives rise to a plenitude of interfaces, both conditions which favour innovative behaviour.

However, in contrast to the initial discovery phase, the downstream drug development process suffers from numerous bottlenecks, which seriously delay the bringing of new promising drug candidates to the market. To remedy this problem, we propose that the European Commission launches a major integrated research and training programme, worth at least 300 million Euro. The ultimate aim of this program is to develop and approve safe and better medicines faster in Europe to the benefit of its citizens. An additional, and vital, aim is to strengthen links between industry, academia, hospitals and regulatory authorities to increase the capacity and speed of development and application of more efficient technologies, to improve information technologies and data management, and to ensure better training of scientists, doctors and regulators.

It is particularly important that civil servants in regulatory agencies and administrative bodies, as well as legislators, are well informed about emerging technologies that may help to develop new and better products and processes. New or improved technologies may also increase the reliability and sensitivity of safety and quality controls. It is of major importance to the competitiveness of European biotech and pharmaceutical industries that these new procedures are introduced quickly and that previous testing protocols, now redundant, are removed without unnecessary delay. Since this is in the common interest of the regulatory agencies and the companies, a constructive dialogue between these parties in the European research area should be encouraged.

Specific suggestions

Science and Recruitment Base:

- Invest substantial resources into the research base of the pharmaceutical/biomedical sciences simultaneously, with more resources for in-depth graduate training, as well as for horizontal broadening of the competencies of selected Ph.D.s and specialists.
- Focus on the implementation of new knowledge through training and education, including better co-ordination and networking between EU schools and faculties engaged in the pharmaceutical and drug development sciences.
- Foster post-graduate training courses, providing trans-disciplinary competencies of relevance to the drug development.
- Reverse the brain drain from the EU by offering very attractive job and training opportunities to the best of its students and scientists, currently working on drug development outside the EU.

Technology and Competence Platforms:

- Develop new technologies that ensure more effective selection, development and approval of new, innovative and safe medicinal products.
- Focus on developing and implementing new ways of testing and approving drug candidates, for instance based on computer assisted drug design, *in-silico* and *in-vitro* toxicity tests, and on advanced data management.
- Support the establishment of more centres for training and development of clinical research and for testing of new technologies.
- Facilitate the organisation of investigator organised pan-European clinical trials.
- Establish concerted efforts to develop and to apply comprehensive IT solutions, to increase the efficiency and speed of drug development.
- Facilitate the rapid incorporation of new technologies and disciplines, as they are discovered and developed; joint efforts between the authorities and the graduate schools are needed, right from the beginning.

Partnerships and Society:

- Cultivate a pan-European interdisciplinary network that bridges the gap between industry, academia, hospitals and regulatory authorities.
- Encourage and support formation of consortia or integrated projects, in joint efforts by academia, hospitals, industry and authorities, to solve major tasks with clear deliverables.
- Open the dialogue between academia, industry and regulatory bodies to reshape and optimise the drug development process.
- Increase the dialogue and mobility between researchers in general; between those working in the scientific community, in industry or in regulatory authorities in particular.

Conclusions

In the continuing effort to offer EU citizens the very best of health services, it is essential to unlock the tremendous power of the pharmaceutical sciences. This can best be achieved through a well-orchestrated effort by all the stakeholders on the European stage to apply this power to move speedily from concept to prescription, from idea to patent, and from knowledge to prevention, treatment, cure and better health. Thus, we believe that implementation of a fine bouquet of the suggestions listed above will benefit patients, improve health and, as an added value, increase the employment and wealth in Europe.

EUFEPS has laid the ground by initiating the New Safe Medicines Faster Project. The outcome of it is, currently, being processed by the European Commission, for incorporation in the 6th RTD Framework Programme. With your strong support and help politicians and civil servants and others in the EU Member States will understand the need and the urgency of it.

Prof. Ole J. Bjerrum
EUFEPS Vice-President and Project Leader

NEW SAFE MEDICINES FASTER

in Europe

will be discussed in a joint session with the

5th Congress of the European Association for Clinical Pharmacology and Therapeutics

September 12-15 • 2001 • Odense • Denmark

This drug discovery and development session is scheduled for September 13, 2001, and it will be chaired and co-chaired by Profs. O.J. Bjerrum (DK), and J. Kuhlmann (DE). Contributions to it include:

- New safe medicines faster in Europe: Why and how (T.M. Jones, UK)
- New safe medicines faster in Europe: Role of academia (S. Garattini, IT)
- Linking preclinical and clinical studies more effectively (T. Guentert, CH)
- Role of the clinical investigator (C. Tulunay, TK)
- How to bring drugs faster to regulatory acceptance: Industry perspective (B. White-Guay, BE)
- How to bring drugs faster to regulatory acceptance: Regulatory agency perspective (G. Alvan, SE)

In total, the EACPT Congress Programme comprises: 3 plenary lectures; 21 scientific sessions; 6 sponsored symposia; 4 satellite meetings; and Poster Presentations. Deadline for submission of abstracts is March 15, and for early bird registration May 1, 2001.

For additional information, including on the submission of abstracts, registration procedures etc., consult the EACPT Congress Website: www.sdu.dk/med/homepages/eacpt/eacpt5.html or contact Prof. Kim Brosen, Institute of Public Health, Clinical Pharmacology, University of Southern Denmark, Winslowparken 19
DK-5000 Odense, Denmark
Tel +45 65 503751
Fax +45 65 916089
Email k-brosen@cefko.sdu.dk

COST B15 Liaison Officers

It is a pleasure to announce that COST B15 has appointed two Liaison Officers to EUFEPS, Prof. Luc Balant (Geneva, Switzerland) for general matters, and Prof. Olavi Pelkonen (Oulu, Finland) for the EUFEPS New Safe Medicines Faster initiative. COST is one of the largest frameworks for research co-operation in Europe. Action B15 deals with “modelling during drug development”.

EUFEPS 2002

New Safe Medicines Faster

October 20-23 • 2002 • Stockholm Sweden

To move the EUFEPS New Safe Medicines Faster initiative forward, it will be put in focus at the EUFEPS 2002, i.e. the 7th European Congress of Pharmaceutical Sciences. New and traditional disciplines in the pharmaceutical sciences will be intertwined with current and emerging aspects of drug research and development. Main programme streams include:

- Drug Design and Discovery
- Exploratory Drug Development
- Human Drug Development
- Drug Use and Utilisation

In addition to oral communications and poster sessions, there will be hot topic discussion sessions, special training workshops, satellite meetings and a major exhibition. Also, while catering for needs of scientists from academia and big pharma, special attention will be given to activities for scientists from CROs (Contract Research Organisations), SMEs (Small and Medium-sized Enterprises), as well as start-up companies.

For additional information, consult the EUFEPS Website: www.eufeps.org (which will be continuously updated), or contact the EUFEPS Secretariat,
PO Box 1136
SE-111 81 Stockholm
Sweden. Tel +46 8 7235000
Fax +46 8 4113217
Email conferences@eufeps.org
or secretariat@eufeps.org

Also, inform your colleagues about the EUFEPS New Safe Medicines Faster initiative and related events.

Dr Károly Nikolics (1918-2000)

Dr Károly Nikolics, late President of the Hungarian Pharmaceutical Society, member of the first presidium of EUFEPS, died on September 15, 2000, after a prolonged illness. His funeral took place at Sopron, his native town, on September 22, 2000, attended with affection and respect by devoted followers, colleagues and disciples.

Dr Károly Nikolics was born in 1918. As a youngster he served as assistant in the pharmacy of his father, and graduated as dipl. Pharmacist at the University of Budapest in 1940. Soon after, in 1943, he received his Doctor of Pharmacy. Because of the ill health of his father he took over the management of the pharmacy, owned by the family. After the nationalisation (expropriation) of pharmacies, in 1950, Dr Nikolics served in another pharmacy of the town of Sopron without interruption until his retirement. This pharmacy was qualified and declared to be a training pharmacy and later as an experimental pharmacy, where he spent many years as a leader.

Throughout his life he was devoted to education, teaching many young pharmacists. Under his tutelage more than 30 of them prepared for the state examination, while 18 wrote their doctoral thesis in pharmacy under the immediate direction of Dr Nikolics.

Beyond his everyday work and teaching, he found time for scientific activities as well. These varied from the exploration of new methods of supervising medicines to the investigation of crystallisation properties of organic substances occurring in drugs. His thesis of candidature dealt with this topic in 1963. He received a degree of Doctor of Sciences in 1977. He was a decisive figure on the editorial board of the Hungarian Pharmacopoeia, and was the chairman or member of several committees of the Hungarian Academy of Sciences.

Dr Nikolics was actively involved in the public life of Hungarian pharmacy. He was elected President of the Hungarian Pharmaceutical Society from 1982 to 1991. International relations of the Society that were abolished during the Soviet occupation were restored during his presidency, as was the FIP membership of the Hungarian Pharmaceutical Society. In 1984, the International Pharmaceutical Federation (FIP) held its congress in Budapest. In 1994, the FIP honoured him with the award of "Lifetime Achievement in the Pharmaceutical Practice", in Lisboa. Dr Nikolics was also active in the creation of the European Federation of Pharmaceutical Sciences (EUFEPS), being a member of its first presidium, and honoured in 1993.

Dr József Lipták, Secretary-General of the Hungarian Pharmaceutical Society (left), and Dr Károly Nikolics, former member of the EUFEPS Executive Committee (right).

Although he never assumed to political roles, his acknowledgement and esteem grew beyond the limits of pharmacy. The President of the first elected Hungarian Government honoured Dr Nikolics with the Medal of Officer's Cross of the Order of the Hungarian Republic, the first man to receive this title. Also, Sopron elected him as a honorary council member of the town.

After retirement he remained active within the Hungarian Pharmaceutical Society. He organised several conferences, and throughout was chairman on the editorial board of the periodical "Gyógyszerészet" (Pharmacy), with a profile centred on professional training.

Dr Károly Nikolics was a scientist with international prestige, in spite of being the leader of a small pharmacy in the small town of Sopron. The pharmaceutical science and practice honoured him, not only for his professional achievements but also for his human qualities as an excellent teacher, colleague and friend of all those who enjoyed his acquaintance.

His death means an irreplaceable loss for the Hungarian as well as for the international communities of pharmacy and the pharmaceutical sciences.

Prof. Zoltán Vincze
President of the Hungarian Pharmaceutical Society

New Trends Symposium

Polymers for Oral and Parenteral Administration: From Design to Receptors

March 12-13 • 2001 • Paris France

This Symposium will deal with all aspects of pharmaceutical polymers devoted to oral and parenteral administration, from their design or modification to their use in formulation and their biological evaluation. It is organised jointly by the European Federation for Pharmaceutical Sciences (EUFEPS), the Groupe Thématique de Recherche sur les Vecteurs (GTRV) and the Association de Pharmacie Galénique Industrielle (APGI). Sessions include:

- Polymer Design for Drug Delivery
- Modified Polymers for Specific Drug Delivery
- Polymers in Formulation Design
- Polymer biological interactions

In addition to plenary lectures, there will be a substantial number of contributed papers, dealing with all areas relating to pharmaceutical polymers for oral and parenteral administration. Plenary lectures and poster abstracts will be printed in the Minutes series published by Editions de Santé, Paris.

For additional information, including on registration and accommodation, contact the Symposium Secretariat at:
APGI/GTRV
Rue Jean Baptiste Clément
FR-92296 Châtenay Malabry Cedex, France
Tel +33 1 46835581 or +33 1 46835627
Fax +33 1 46835308 or +33 1 46835853
Email apgi.apgi@cep.p-sud.fr
or gillian.barratt@cep.u-psud.fr
Also, inform your colleagues about this important event.

Optimising Drug Development Conferences

The EUFEPS Conference on Optimising Drug Development is a unique discussion forum for scientists from the pharmaceutical industry, regulatory agencies and academic institutions. Seven successful conferences were organised in this series. In 2001, there will be two conferences, one in "exploratory drug development" and one in "human drug development".

Strategies to the Rational Design of Drug Material and Drug Delivery Systems – Towards a Consensus

September 20-21 • 2001 • Strasbourg • France

Pharmaceutical and biopharmaceutical performances of new chemical entities (NCE) are largely dependent on the formulations and/or drug delivery systems available for their study. This Conference will focus on how to select and design the drug material, the formulations and/or the drug delivery systems that will be needed for NCE developability assessment (bioavailability, manufacturability, stability), as well as on how to conduct the studies from lead identification to first in man. Sessions include:

- Polymorph/Solid State Variation Prediction
- *In vitro* Bioavailability Assessment
- *In vivo* Bioavailability Assessment
- Drug Delivery Systems Design
- The Regulatory View
- Discussion of Break-out Session Reports and Position Statements

The Conference Leadership include: Per Artursson (Co-Chair; Sweden), Henning Kristensen (Co-Chair; Denmark), Dr Michel Veillard (Co-Chair; France).

Use of Biomarkers and Regulatory Decision Making

December 10-12 • 2001 • Basel • Switzerland

This Conference intends to discuss scientific opportunities, and need, to improve the identification of biomarkers in disease and their use in assessing therapeutic interventions during the process of drug development and regulatory decision making. It will bring together industrialists, academicians, and regulatory scientists, trying to identify areas of agreement on key issues in the field, and areas of disagreement with ways forward toward resolution. Sessions include:

- "Setting the stage" – definitions, terminology, origin of biomarkers, current status and needs in drug development and regulatory decision making
- Biomarkers for safety and efficacy assessment – from preclinical studies to the end of the early clinical phase of drug development (II B)
- Biomarker applications and value in late clinical phase drug development and life cycle management
- Biomarker applications in regulatory decision making
- Where do we go from here – discussion of Break-out Session Reports and Position Statements

The Conference Leadership include: Art Atkinson (Co-Chair; USA), Ole J. Bjerrum (Denmark), Fritz Bühler (Switzerland), Meindert Danhof (The Netherlands), Anders Grahnén (Sweden), Larry Lesko (Co-Chair; USA), Paul Rolan (Co-Chair; UK), Malcolm Rowland (UK).

Consult and Communicate

For additional information on these EUFEPS Optimising Drug Development Conferences, consult the EUFEPS Website: www.eufeps.org (which will be continuously updated), or contact the EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Tel +46 8 7235000. Fax +46 8 4113217. Email conferences@eufeps.org or secretariat@eufeps.org Also, inform your colleagues about these important events.

XVI Helsinki University Congress of Drug Research

Polymers for Oral and Parenteral Administration: From Design to Receptors

June 7- 8 • 2001 • Helsinki Finland

This biennial international meeting is jointly organised by the Department of Pharmacy of the University of Helsinki, the Finnish Centre for Continuing Pharmaceutical Education and the Finnish Pharmaceutical Society, and it is co-sponsored by EUFEPS. At this Congress, the drug discovery process is in focus: the design, synthesis and screening of drugs, as well as pharmacological and pharmacokinetic studies and drug formulation. Delegates include young and advanced scientists in the field of pharmacy, medicine and related natural sciences.

Topics of the 2001 symposia are:

- Brain dopamine as source for drug discovery
- Early ADME in drug discovery and development
- Higher throughput screening of pharmaceutical compounds
- Crystal Space Odyssey 2001

In addition, there will be plenary lectures, posters and a commercial exhibition.

February 15, 2001, is deadline for submission of abstracts. Accepted abstracts will be published in an Supplement of the European Journal of Pharmaceutical Sciences.

For additional information, visit the Research Congress Website:
www.biocenter.helsinki.fi/drugres
or contact
Prof. R.K. Tuominen
Division of Pharmacology and Toxicology
Department of Pharmacy
P.O. Box 56
FIN-00014 University of Helsinki, Finland
Tel +358 9 19159469
Fax +358 9 19159471
Email raimo.tuominen@helsinki.fi

Posttidning B EUFEPS Newsletter
PO Box 1136
SE–111 81 Stockholm
Sweden

C A L E N D A R

Particle Size, Characterisation and Surface Area Measurement of Materials
February 12-14, 2001, London, UK
Contact: European Continuing Education College, 24 Menlove Gardens North, Liverpool L18 2EJ, UK, Fax +44 151 7371070
Email info@ecec.co.uk

*

Rational Fytotherapy: Clinical Trials on Herbal Medicinal Products
February 14, 2001, Stockholm, Sweden
Contact: Swedish Academy of Pharmaceutical Sciences, P.O. Box 1136, SE-111 81 Stockholm, Sweden, Fax +46 8 205511
Email annette.lindberg@lakemedelsakademin.se

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Modern Methods of Pharmaceutical Analysis
February 19-21, 2001, London, UK
Contact: European Continuing Education College, 24 Menlove Gardens North, Liverpool L18 2EJ, UK, Fax +44 151 7371070
Email info@ecec.co.uk

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3rd European Graduate Student Meeting
February 23-25, 2001, Frankfurt/Main, Germany
Contact: Prof. Theo Dingermann, Institute for Pharmaceutical Biology, Biozentrum, Marie-Curie-Strasse 9, DE-60439 Frankfurt/Main, Germany
Fax +49 69 79829662
Email dingerman@em.uni-frankfurt.de
Website www.eufeps.org

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Arden House 6th Annual European Conference
February 25 – March 1, 2001, Cambridge, UK
Contact: J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk
Website www.rpsgb.org.uk

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Principles and Design of Pharmaceutical and Biotechnology Production Facilities
March 5-8, 2001, London, UK
Contact: European Continuing Education College, 24 Menlove Gardens North, Liverpool L18 2EJ, UK, Fax +44 151 7371070
Email info@ecec.co.uk

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Advanced Course on Biocatalysis
March 5-9, Delft, The Netherlands
Contact: Biotechnology Studies Delft Leiden (BODL), Dr L.A. van der Meer-Lerk, Delft University of Technology, Julianalaan 67, NL-2628 BC Delft, The Netherlands
Fax +31 15 2782355, Email bodl@tnw.tudelft.nl

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Validation of Changes in Analysis of Pharmaceuticals
March 8, 2001, London, UK
Contact: J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397, Email jclements@rpsgb.org.uk
Website www.rpsgb.org.uk

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Tablet and Capsule Machine Instrumentation and Automation
March 12-14, 2001, London, UK
Contact: European Continuing Education College, 24 Menlove Gardens North, Liverpool L18 2EJ, UK, Fax +44 151 7371070
Email info@ecec.co.uk

New Trends in Polymers for Oral and Parenteral Administration
March 12-13, 2001, Paris, France
Contact: APGI, Rue Jean Baptiste Clément, FR-92296 Châtenay Malabry Cedex, Fax +33 1 46835308, Email apgi.apgi@cep.u-psud.fr
Website www.eufeps.org

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QA-TQM-Course, module 6: Food technology and food safety
March 12-14, 2001, Wageningen, The Netherlands
Contact: Biotechnology Studies Delft Leiden (BODL), Dr L.A. van der Meer-Lerk, Delft University of Technology, Julianalaan 67, NL-2628 BC Delft, The Netherlands
Fax +31 15 2782355, Email bodl@tnw.tudelft.nl

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Current Requirement for Chemistry and Pharmacy Sections of Regulatory Submissions
March 21-23, 2001, London, UK
Contact: European Continuing Education College, 24 Menlove Gardens North, Liverpool L18 2EJ, UK, Fax +44 151 7371070
Email info@ecec.co.uk

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Advanced Methods in Pharmacokinetics and Pharmacodynamics: A one week Workshop
March 25-30, 2001, San Francisco, USA
Contact: Advanced Pharmacokinetics, c/o Make It Happen, 137 Alhambra Street, San Francisco, CA 94123, USA, Fax +1 415 5678667
Website www.plessthan.com/course/

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Cannabinoids – from Plant to Patient
April 5, 2001, London, UK
Contact: J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk
Website www.rpsgb.org.uk

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Analytical Approaches to the Development of Biotechnology Products: the Science and the Regulatory Process
April 26-27, 2001, London, UK
Contact: J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk
Website www.rpsgb.org.uk

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Clinical Trials – A methodologic perspective
May 7-10, 2001, Lunteren, The Netherlands
Contact: Ms Astrid van Alst, Dept. of Epidemiology & Biostatistics/252, University Medical Centre Nijmegen, P.O. Box 9101, NL-6500 HB Nijmegen, The Netherlands
Fax +31 24 3613505, Email a.vanalst@mie.kun.nl

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Advanced Course on Downstream Processing
May 7-11, Delft, The Netherlands
Contact: Biotechnology Studies Delft Leiden (BODL), Dr L.A. van der Meer-Lerk, Delft University of Technology, Julianalaan 67, NL-2628 BC Delft, The Netherlands
Fax +31 15 2782355, Email bodl@tnw.tudelft.nl

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Course on Pharmacokinetic-Pharmacodynamic Modeling: Concepts and Applications
May 20-23, 2001, Buffalo, N.Y., USA
Contact: Ms Sandra Wheaton, University at Buffalo, Dept of Pharmaceutics, School of Pharmacy, Hochstetter Hall Rm. 565, Box 601200, Buffalo, NY 14260-1200
Fax 01 716 6453693,
Email wjjusko@acsu.buffalo.edu

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3rd Advanced Level Workshop PK/PD Data Analysis: A hands-on course using WinNolin
May 20-24, 2001, Cambridge, UK
Contact: J.A. Clements, Room 403, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 171 5820397
Email jclements@rpsgb.org.uk
Website www.rpsgb.org.uk

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14th IFCC-FESCC European Congress of Clinical Chemistry and Laboratory Medicine EUROLAB 2001
May 26-31, 2001, Prague, Chech Republic
Contact: Euromedlab Secretariat,Institute for Clinical Biochemistry and Diagnostics, University Hospital, CZ-50005 Hradec Kralove, Czech Republic, Fax+420 49583 2003
Email euromedlab@lfhk.cuni.cz

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World Conference on Drug Absorption and Drug Delivery
June 18-20, 2001, Copenhagen, Denmark
Contact: EUFEPS Secretariat, PO Box 1136 SE-111 81 Stockholm, Sweden
Fax +46 84113217
Email conferences@eufeps.org
Website www.eufeps.org

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Advanced Course on Environmental Biotechnology
June 20-29, 2001, Delft, The Netherlands
Contact: Biotechnology Studies Delft Leiden (BODL), Dr L.A. van der Meer-Lerk, Delft University of Technology, Julianalaan 67, NL-2628 BC Delft, The Netherlands
Fax +31 15 2782355, Email bodl@tnw.tudelft.nl

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9th International Congress of Toxicology
July 8-12, 2001, Brisbane, Australia
Contact: Congress Secretariat, 11/97 Castlemain St, P.O. Box 1280, Milton QLD 4064, Australia
Fax +61 7 38585510
Email ictix2001@im.com.au
Website www.uq.edu.au/ict9

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Strategies to the Rational Design of Drug Material and Drug Delivery Systems
September 20-21, 2001, Strasbourg, France
Contact: EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Fax +46 8 4113217 Email conferences@eufeps.org
Website www.eufeps.org

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Optimising Drug Development: Use of Biomarkers and Regulatory Decision Making
December 10-12, 2001, Basel, Switzerland
Contact: EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Fax +46 8 4113217 Email conferences@eufeps.org
Website www.eufeps.org