EUFEPS

NEWS Letter

European Federation for Pharmaceutical Sciences September 2002 Vol 11 No3

EUFEPS Secretariat

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Lay-out

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Welcome to EUFEPS 2002!

In a few weeks (October 20th – 23rd), EUFEPS 2002 will open at the Stockholm International Fairs, Stockholm, Sweden.

The attractive programme of this major congress reflects the profound changes that have taken place in pharmaceutical R&D in recent years. This means that you will see and hear more interdisciplinary lectures in the the four streams viz. Drug Design and Discovery, Exploratory Drug Development, Human Drug Development and Drug Use and Utilisation. About 250 posters will be presentated, organised in the traditional way within the scientific pharmaceutical disciplines.

The overall theme of the congress is New Safe Medicines Faster, which has its origin in a EUFEPS project initiative started in year 2000. This initiative, encouraged by the European Commission, aims to support the research necessary for the development of new, safe medicines faster in Europe.

These two concepts of an interdisciplinary flavour and NSMF were in focus when the scientific programme was created and organised under the chairmanship of Professor Douwe D. Breimer. This excellent mixture of plenary lectures and parallel sessions will offer presentations at the highest scientific level.

In addition to the scientific sessions, there will be an interesting series of Afternoon Specials (supported by the European Commission), where you can discuss “hot topics” such as education and training, ethics, clinical trials, promotion of science-driven regulation, the role of start-up companies, east-west scientific integration in Europe, innovation in NCE development, pharma/public interface, etc. Two slots of Specials will provide extensive information from representatives of The European Commission about the EU 6th Framework Programme, as well as the results of those Expressions of Interest (EoI) relevant to the pharmaceutical sciences.

A congress such as EUFEPS 2002 willwould not be complete without an Exhibition. Therefore, we have organised exhibits, together with the Stockholm International Fairs, which will display the latest in instrumentation and services in pharmaceutical research for the benefit of the visitors.

Not least, the city of Stockholm welcomes you to spend a few days in connection with the 750th anniversary of the beautiful capital of Sweden.

Professor Jürgen Vessman
Chair EUFEPS 2002 Organising Committee

November 15, 2002, is the deadline for announcements and manuscripts for the next issue of the EUFEPS Newsletter

LEADER

A need for Excellence in Pharmaceutical Sciences

The scene

At the present time, the pharmaceutical sciences in Europe are both under pressure and increasingly supported. This paradox derives from the rapid changes that our society is going through technologically and structurally. Until now, the main body of the pharmaceutical sciences has been taught in Schools or Faculties of Pharmacy within universities.

However, many of the classical roles of the individual practising pharmacist are diminishing while other roles are actually increasing e.g. due to polypharmacy and the evolution in the preventive use of drugs. In many European countries, the industry's demand for pharmacists is increasing leading to requests for new topics in the educational curriculum.

These trends have put a squeeze on the present structures of the pharmacy institutions. Generally speaking, if the adaptations required to meet the challenges of the new developments and the needs of the industry are not implemented, one may fear that the present school structures in many places will not survive.

The wrong response

Since the half-life of scientific and technological advances is much shorter than the half-life for turnover of academic scientists, it is sometimes difficult for the latter to keep pace with the changes if not active in research. Falling back on well-established privileges may delay the process locally but overall it will not avoid the need for adjustments in the longer term.

The right response

It is much better to be open to the current trends, before they finally result in demands from politicians. The new openings, which are structural as well as economic, should be exploited proactively. The essence is to have enough money to be in a position to protect the key values of the educational disciplines. The training in the schools of pharmacy should be potentiated with addition of new courses e.g. (bio)technology and economics. Also new curricula developed together with schools in other European countries should be considered as European Master degrees. It is probable that the medicines distribution system will undergo major changes in the future, which ultimately will result in a reduced need for the classical dispensing role of the pharmacist.

To survive the pressure, it is important for the pharmaceutical world to be strong. We have to strive for excellence in all that we do, including the sciences, which are our foundations.

Where are the positive trends?

A major opportunity lies in reorientation with the many new stakeholders involved in discovery, development, production and consumption of medicines. The economic activity here increases every day and with that the involvement of pharmacists. In other words, the drug development process as a whole represents an expanding market. Note that under such conditions it is much easier to become a significant player in the market if so wished.

Where to get strength

Since the foremost dominating player in this connection is the pharmaceutical industry, the likeliest orientation is to their needs, but don't neglect the other players if your scientific and organisational strengths point in their direction. The future lies in collaborative arrangements including the pharmaceutical industry and the medical and health professional world. When the concept of individualised therapies gains momentum, closer relations to the clinical arena are essential.

What is excellence?

Scientists are open to fair competition as it is seen through the refereeing system for articles in scientific journals, for example. Thus the route to excellence for results and "products" goes through comparison and competition. To have enough space for this, the national scene often is too narrow, at least for many small countries. For this reason, competition at the European level is the rational next step in the process of reaching for excellence.

How to reach excellence

If you want to reach excellence this can happen through:

1. Competition for national and supranational money (from EU).
2. Potentiation of interdisciplinary research.
3. Optimisation of your actual critical mass, for example, through mergers, alliances, collaborations, and network creations.
4. Preferential research carriers at universities.

Just now, there is no excuse for not trying these routes, as the pharmaceutical sciences are stated topics in the 6th EU Framework Programme (FP6) starting in 2003. Remember when the scientific topics are first defined, money for all accompanying measures linked to these topics is released.

Some of the many pharmacy institutions in Europe have a tradition of international collaboration but many keep back because they don't consider themselves to be strong enough for partnering. Nothing is more wrong. There is room for you if you want. Look out for alliances, networks, collaborations and consortia. Here it is important to remember that collaboration does not necessarily need to be with others of your kind. By the involvement of other stakeholders of the drug development process i.e. disparate scientific disciplines, start-up companies and established industries, medical doctors and hospital providers, medicinal agencies and other authorities, you will be helped on your way. The list of "Expressions of Interest" for future EU applications, published elsewhere in this issue, could function as a first map for such networking.

EUFEPS role

Not all results and products can be submitted for competition in a European context and thereby be selected for excellence, for example for obtaining financial support through FP6. For this reason, the level of excellence has to be defined in additional ways.

Since EUFEPS represents all the pharmaceutical sciences in Europe it also represents the natural platform for setting common European denominators for excellence regarding education, science and training, as well as other issues of common interest for the pharmaceutical scientific community as a whole. Indeed this is part of EUFEPS strategy for 2002-2006, which will be presented at the Council meeting in Stockholm on 20th October 2002.

Last words

Thus if you want excellence in pharmaceutical sciences:

- European standards are in demand – a strong EUFEPS is necessary.
- Exploit EUFEPS – the federation may help you.
- Support EUFEPS – you are needed.

Ole J. Bjerrum
EUFEPS Vice President

International Meeting on

Molecular Biopharmaceutics:

A New Era in Drug Absorption Transport and Delivery

January 22 - 24 • 2003 • Sheraton Waikiki Resort • Hawaii

This event is replacing the former Japan/American Biopharmaceutics and Pharmacokinetics Meeting, and it is the second one in the new series of World Conferences on the topic, which started in Copenhagen, Denmark, in June 2001. The ones to follow should appear in Europe in 2005 and in Japan in 2007.

Topics

New Molecular Technologies for Biopharmaceutics: Meeting the Genomic Challenge (Workshop) • Molecular and Cellular Aspects of Drug Absorption and Transport: Membrane Transporters and Diffusion • Molecular Advances in Metabolism and Transport: Intestine, Liver, Kidney • Molecular Aspects of Tissue Barriers: Cellular and Sub-Cellular Mechanisms • Molecular Approaches to Gene Delivery and Biopharmaceuticals • Cellular and Molecular Approaches to ADME Screening Delivery Strategies for Problem Compounds • Pharmacogenetics and Biopharmaceutics: New Challenges for Drug Discovery, Development, and Regulation

Posters and Exhibition

Deadline for submission of abstracts is October 30, 2002. Exhibitor space is being offered for a package price.

Conference Co-Chairs

Gordon L. Amidon, Ann Arbor MI USA • Akira Tsuji, Kanazawa JP • Peter Langguth, Mainz DE

Co-sponsors

American Association of Pharmaceutical Scientists (AAPS) • Academy of Pharmaceutical Science and Technology, Japan (APSTJ) • Japan Society for the Study of Xenobiotics (JSSX) • European Federation for Pharmaceutical Sciences (EUFEPS)

Additional information

For more information, access the Conference Website:
http://www.ddfint.org/hawaii.htm
or contact the Drug Delivery Foundation International, Attn: Shona Johnson via email sjohnson@ddfint.org or call +1 734 6634233 ext. 243,
or send fax +1 734 6633607.

Expressions of Interest (EoIs) for the pharmaceutical sciences

The European Commission received an overwhelming response from the scientific community. More than 15,000 EoI's were received. The number of these that are relevant for the pharmaceutical sciences will be revealed by the Commission, at the EUFEPS 2002 Congress in Stockholm on 21st October. EUFEPS is aware of the following relevant Expressions:

- A European programme for bioseparation of modern biopharmaceuticals: Integrated project by Alois Jungbaue, Vienna. (EUFEPS involved)
- ATP-Binding Cassette /ABC Protein Research Centers: A Network of Excellence to Combat Resistance & Genetic Diseases by Karl Kuchler, Vienna.
- Biosimulation – A new tool in drug development: Network of Excellence by Erik Mosekilde. Copenhagen. (EUFEPS involved)
- European network for a acceleration of biopharmaceutical drug and vaccine candidate GMP development (ENABLE) by Holger Ziehr, Braunschweig. (EUFEPS mentioned)
- Galenos-Network in Advanced Drug Delivery: Network of Excellence by C. M. Lehr, Saarbrücken.
- Individualized therapies in the postgenomic area: Network of Excellence by Ole J. Bjerrum, Copenhagen for ULLA. (EUFEPS mentioned)
- Membrane transporters: their role in drug ADME and cancer resistance: Integrated Project by Marival Bermejo, Valencia.
- Pathology/G-protein complied receptors Drug – Consortium: Network of Excellence by Jacques Haiech, Strasbourg.
- Polyamines and Plants: Network of Excellence by Christian Noe, Vienna.

Accompanying measures in FP6 available for pharmaceutical purposes

Implementation of new techniques
Introduction of new methodologies and individualised therapies
Workshops, meetings, conferences
Training courses
New education
Marie Curie fellowships
Networking
Infrastructures incl. libraries of any kind regarding data, specimens, biopsies, genetically modified animals, etc.
Creation of companies
Intellectual property rights

Your application is favoured if it contains selected partners from surrounding stakeholders like industry, regulatory agencies, hospitals and their providers, patient organisations and ethical bodies. All these partners could help you to bring safer, more economically and affordable medicines to the patient faster.

Executive Summary • September 2002

There has been no meeting of the Executive Committee since the latest Newsletter. Next meetings are scheduled for mid-September in Istanbul, and for the latter part of October, in conjunction with the EUFEPS 2002 Congress and Council meeting in Stockholm.

Successful training course

The EUFEPS two-weeks Training Course on High-throughput (HT) Drug Metabolism/-Disposition was successfully completed at the beginning of July, in Amsterdam. Course leaders were Profs. Nico Vermeulen and Jan Commandeur. After evaluation, it will be decided about the next course on this topic.

EUFEPS 2002 and programme

Preparations for the Congress on "New Safe Medicines Faster", this year organised by EUFEPS itself, have taken much of the Secretariat time during the past several weeks, and will until October. Altogether, there are more than one hundred invited speakers on the programme. Close to 250 poster abstracts were received, and the poster area will be combined with the breaks and exhibition area of the Congress to facilitate maximum interaction. "Afternoon Specials" will highlight special issues related drug research and development. There are also keynote addresses, an Awards Ceremony, a Stockholm City Hall Reception and a Congress Dinner. For update, consult the EUFEPS Online (www.eufeps.org). For additional progress of the EUFEPS New Safe Medicines Faster Initiative, see other information in this issue.

Strategy and elections

Sunday October 20 will be the Council day, this year. The Council Open Forum, established two years ago, will be held in the morning and the formal Council Meeting in the afternoon, both in the premises of the Swedish Pharmaceutical Society in central Stockholm. Important items on the Council Agenda include the EUFEPS Strategic Plan 2002-2006, proposed amendments to the EUFEPS Statutes and elections to the Executive Committee. The new candidates are: Prof. Conny Bogentoft (Sweden), Dr Altan Demirdere (Turkey), Prof. Ales Mrhar (Slovenia) and Prof. Christian Noe (Austria).

New meetings platform

Several months ago, the EUFEPS President invited the EUFEPS Member Societies, as well as an additional substantial number of European associations, societies and federations, to participate in a meeting on September 3, 2002, in Nice, France. The aim was to discuss whether European forces should be joined to establish a new European meetings platform for the pharmaceutical sciences. At the meeting, it was agreed to proceed and a further discussion was scheduled, for December 6, 2002, in Brussels.

Hans H. Lindén,
Secretary-General & Treasurer.

Pharmacopoeias, more than the books alone

In this article, Prof. Henk de Jong, who is a liaison between EUFEPS and the USP, describes the value and accessibility of pharmacopeial information.

Everybody working in the field of pharmacy knows about Pharmacopoeias.

The modern Pharmacopoeias contain collections of monographs describing test methods and limits for pharmaceutical ingredients and (in some of them) for dosage forms. The Pharmacopoeial Discussion Group (PDG), a combined effort of the Japanese Pharmacopoeia (JP), the European Pharmacopoeia (Ph.Eur) and the United States Pharmacopeia/National Formulary (USP/NF), has tried, since more than 10 years now, to harmonise test methods and limits, thus setting worldwide standards, in line with another international effort: The International Conference on Harmonization (of technical requirements for the registration of medicinal products) known as ICH.

The JP is part of the government in Japan, the Ph.Eur. is the fruit of an international convention under the aegis of the Council of Europe and the oldest of the three. The USP, is a private volunteer organisation. These different legal statuses offer possibilities but also impose limits on the freedom of action of these bodies. In Japan a close link exists with the National Institutes of Health Sciences, the government laboratories and institutes providing scientific expertise. In Europe, the Ph.Eur is now part of the European Directorate for the Quality of Medicines deploying activities like Certification, networking of National Official Control Laboratories as well as organisation of seminars and congresses.

For a long time, the USP has given information to health care providers and the general public, in addition to the "traditional" work on the Pharmacopeia itself. Open conferences, workshops, seminars and the Quinquennial Convention, where all stakeholders meet, have been and are important vehicles for information transfer and generation. EUFEPS is one of the organisations that has a representation in the Convention (at present, there are 436 organisations within the Convention). As EUFEPS' representative to the USP Convention and as an active member of the European Pharmacopoeia Commission, with friendly contacts to the JP Society, I hope to give you pharmacopoeial news on a regular basis. Here is a first communication.

– The Japanese Pharmacopoeia Ed. XIV, English version, is freely available at: http://jpdb.nihs.go.jp/jp14e. For people able to read Japanese: The general nihs site (without the /jp14e extension) contains information related to regulations, sciences and medicine.

– The European Pharmacopoeia now exists as a paper version, a CD-ROM version and an on-line version. All are paying services, details are to be found at: http://online.pheur.org. The (free) general website: http://www.pheur.org gives a lot of information, including the table of contents of Pharmeuropa, the magazine containing scientific articles and all proposals for new or modified monographs next to announcements of seminars and conferences.

– The USP/NF also has paper and CD-ROM versions, which are both paying services. The website http://www.usp.org is a very rich free source of information. For people in a hurry: A look in the /e-newsroom under "Media Kits" gives you summaries of important news and policies. Over the last few months we have seen information on MedMARx the program on medication errors, which is a follow up to the Drug Product Problem Reporting Program that was started by USP in the 1970s.

Also the trend analysis in Prescription Drug Utilization is of great interest to people involved in Medicines Development and Health Economics.

Professor Henk J. De Jong
SERVIER International Research Institute, France
and Leiden Amsterdam Centre for Drug Research, The Netherlands.

Groundbreaking Workshop on

Assuring Quality and Performance of Sustained and Controlled Release Parenterals

Basel Convention Center • February 17-18 • 2003

Scope and aim

This Workshop follows on from the one held in Washington DC USA in April 2001. It will cover dispersed systems (microspheres, liposomes, gels and suspensions), as well as implants of small molecules and protein/peptide therpeutics for human and animal use, in plenary lectures, breakout sessions and other discussions. It will bring together industrialists, academics, and regulatory scientists to identify future directions for regulatory activity and public standards in this rapidly emerging area.

Goals and objectives include:

To review formulation, processing and manufacture of CR parenterals.

To identify and discuss critical process parameters and their control.

To identify new, emerging methods of in vitro release testing for CR parenterals and their ability to predict product performance.

To discuss accelerated stability and in vitro release testing methods for CR parenterals.

To discuss bioavailability, bioequivalence and pharmaceutical equivalence for CR parenterals.

To explore the opportunity for in vitro-in vivo correlation of CR parenterals.

To provide input for a Workshop Report for future directions for regulatory activity and public standards in this area.

Exhibition and Posters

Scientific contributions relating to the conference topic will be welcome and considered for poster presentations. Abstracts should be submitted to the EUFEPS Secretariat, both as an email attachment and as a hard copy, before December 18, 2002. Editorial instructions for the abstract are posted on the EUFEPS Website.

Companies are invited to exhibit at this Conference, particularly in the areas of particle size measurement, in vitro release testing of controlled release parenterals, formulation and manufacturing of controlled release parenterals, and parenteral excipients. Exhibitors will also be given a few minutes slot in one section of the Programme, to focus on their input to the field. Companies interested in exhibiting should contact the EUFEPS Secretariat for further information on layout and costs etc. A "Best Scientific Contents Award" will be considered.

Additional information

For more information, consult the EUFEPS Website or contact the EUFEPS Secretariat. Also, tell your colleagues about this important Workshop!

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SE-111 81 Stockholm, Sweden
Fax +46 8 4113217. Tel +46 8 7235000.
Email conferences@eufeps.org
Website www.eufeps.org

EUFEPS 2002: New Safe Medicines Faster
October 20-23, 2002, Stockholm, Sweden
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 4113217
Email secretariat@eufeps.org
Website www.eufeps.org

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Biological Membranes: Permeation Barriers and Drug Targets
November 4-8, 2002, Copenhagen, Denmark
Contact: Ass.Prof. Harald S. Hansen and Ass.Prof. Birger Brodin Larsen, Royal Danish School of Pharmacy, Universitetsparken 2
DK-2100 Copenhagen Ø, Denmark
Fax +45 35 306001

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V Spanish-Portugese Conference on Controlled Drug Delivery
November 10-13, 2002, Seville, Spain
Contact: Mercedes Fern·ndez Arévalo, Dept. of Pharmaceutical Technology, University of Seville, Spain, Fax +34 95 4556726
Email arevalo@farfar.us.es

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New Tools and Concepts for the Medicinal Chemist
November 21-22, 2002, Amsterdam, The Netherlands
Contact: R. Leurs, LACDR, De Boelelaan 1083
NL-1081 HV Amsterdam, The Netherlands
Email far@chem.vu.nl

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Tabletting Technology
November 25-27, 2002, Cambridge, UK
Contact: Dr J.A. Clements, Room 304, Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 7572 2506
Email science@rpsgb.org.uk
Website www.rpsgb.org.uk/science

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10th EUFEPS Conference on Optimising Drug Development: Getting teh Dose Right
December 9-11, 2002, Basel, Switzerland
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 4113217
Email secretariat@eufeps.org
Website www.eufeps.org

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XVII Journees Scientifiques du GTRV
December 12-13, 2002, Paris, France
Contact: Catherine Passirani
Phone +33 2 41735850
Email: Catherine.passirani@univ-angers.fr
Website www.gtrv.u-psud.fr/gtrv

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3th Pharmaceutical Technology Meeting of the Spanish Association of Industrial Pharmacists
February 9-11, 2003, Granada, Spain
Contact: Juan J. Torres Labandeira, Facultad de Farmacia, Campus Universitario Sur, ES-15782
Santiago de Compostela, Spain
Fax +34 981 547 148, Website www.sefig.com

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AAPS Workshop on Drug Transport: From Bench to Bedside
February 10-12, 2003, Peachtree, GA, USA
Contact: www.aapspharmaceutica.com/meetings/drugtransport/index.asp

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Groundbreaking Workshop on Assuring Quality and Performance of Sustained and Controlled Release Parenterals
February 17-18, 2003, (NEW DATE!) Basel, Switzerland
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 4113217
Email secretariat@eufeps.org,
Website www.eufeps.org

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21st Pharmaceutical Technology Conference & Exhibition
March 11-13, 2003, Dublin Ireland
Contact: The Conference Secretary
21st Pharmaceutical Technology Conference
24 Menlove Gardens North, Liverpool L18 2EJ, UK, www.pharmtechexhibition.com

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Arden House European Conference
March 24-26, 2003, London, UK
Contact: Dr J.A. Clements, Room 304, Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 7572 2506
Email science@rpsgb.org.uk
Website www.rpsgb.org.uk/science

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Pharmacogenomics in Drug Research and Development – from Drug Discovery to Marketing, Possibilities and Pitfalls
April 7-11, 2003, Copenhagen, Denmark
Contact: Ass.Prof. Claus Moldrup, Royal Danish School of Pharmacy, Universitetsparken 2
DK-2100 Copenhagen Ø, Denmark
Fax +45 35 306001

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International Society for the Study of Xenobiotics. 8th European ISSX Meeting
April 27-May 1, 2003, Dijon, France
Contact: ISSX, P.O. Box 3, Cabin John, MD 20818, USA, Fax +1 301 9835357
Email nholahan@issx.org

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32nd Meeting of the Histamine Research Society
May 7-11, 2003, Noordwijkerhout, The Netherlands
Contact: H. Timmerman, LACDR, De Boelelaan 1083, NL-1081 HV Amsterdam
The Netherlands, Fax +31 20 4447610
Email ehrs@chem.vu.nl

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Course on Pharmacokinetic-Pharmacodynamic Modeling: Concepts and Applications
May 18-21, 2003, Buffalo, N.Y., USA
Contact: Ms Sandra Wheaton, University at Buffalto, Hochstetter Hall, Box 601200, Buffalo NY 14260-1200, Fax +1 716 6453693
Email wjjusko@acsu.buffalo.edu

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5th Advanced Level Workshop on Pharmacokinetic/Pharmacodynamic Data Analysis
May 18-22, 2003, Cambridge, UK
Contact: Dr J.A. Clements, Room 304, Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 7572 2506
Email science@rpsgb.org.uk
Website www.rpsgb.org.uk/science

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International Analytical Validation and Regulatory Issues for the Pharmaceutical Industry
July 9-11, 2003, York, UK
Contact: Dr J.A. Clements, Room 304, Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 7572 2506
Email science@rpsgb.org.uk
Website www.rpsgb.org.uk/science

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7TH Eilat Conference on New Antiepileptic Drugs
May 9-13, 2004, Eilat, Israel
(with backup site in Italy)
Contact: Target Tours Ltd, Eilat VII, Box 2904
Tel Aviv 61290, Israel, Fax +972 3 5175155
Email eilatvii@targetconf.com
Website www.eilatvii.com

Stem Cells: therapies for the future?

The European Commission in line with its Action Plan on "Science and Society" and "ìLife Sciences and Biotechnology: a Strategy for Europe", is encouraging the involvement of research scientists at all levels of the public debate. Commissioner Philippe Busquin, with responsibility for Research, has created a European Group for Life Sciences to help form a vision of life sciences and their future development and impacts on European citizens. In order to help the process of information sharing and consensus forming, opportunities have been created for focused debates on various sensitive issues.

A brochure entitled "Stem Cells: Therapies for the Future", reflecting the highlights of a discussion platform in Brussels (18-19 Dec 2001) with 700 participants can be found at: http://europa.eu.int/comm/research/quality-of-life/stemcells.html.

The European Parliament finally approved FP6 on May 16, 2002

The 17.5 billion Euro programme, which will run from 2003 to 2006, was approved with some 34 compromise amendments agreed between the Parliament, Council and Commission. The amendments reflect a desire to place emphasis on tackling serious diseases such as cancer and those which affect children.

The support to accelerated development of new safe medicines is untouched, and it is stated to be independent of genomic research.

Owing to divisions between the Member States, ethics was left out of the Councilís common position. The Commission intends to address this issue by appending a declaration in which, during the first year, it undertakes not to finance any research involving genetic manipulation, human cloning or the creation of embryos for research purposes. Thereafter, new rules should be in effect.

Ole J. Bjerrum

10th EUFEPS Conference on

Optimising Drug Development: Getting the Dose Right

Jointly organised with the European Center of Pharmaceutical Medicine's Workshop Series on Frontiers in Drug Development

Basel Convention Center • December 9–11 • 2002

As with previous Conferences there will be a unique and intensive discussion forum with plenary lecturers, break-out sessions and final reports, bringing together colleagues from pharmaceutical and biotechnology industries, academia, and regulatory agencies.

Preliminary Programme

Opening Session

- Opening of the Conference
  Dominique Duchêne, EUFEPS President, Paris FR
- Introduction to the programme
  Fritz R. Bühler, Basel CH
- Achievements of past conferences and future goals
  Ole J. Bjerrum, Copenhagen DK

Session I: Highlighting current problems

Chairman: *Malcolm Rowland*, Manchester UK

- A modern view of dose-response: Beyond the minimum effective dose
  Lewis Sheiner, San Francisco CA USA
- The magnitude of adverse events related to dose
  Bert Leufkens, Utrecht NL
- Post-marketing dosage changes: What are the reasons why?
  James Cross, Rockville MD USA

Session II: Reengineering drug development and role of exposure response assessment

Chairman: *Fritz R. Bühler*, Basel CH

- Potentials to reengineer clinical drug development
  William Jenkins, Basel CH
- Incorporation of exposure response information into drug development
  Carl C. Peck, Washington DC USA

Session III: Efficient and informative alternatives for classical approaches

Chairman: *Paul Rolan*, Manchester UK

- Novel designs to improve dose-response understanding
  Niclas Jonsson, Uppsala SE
- Enrichment strategies to optimise dose-response for efficacy
  Harry J.M. Lemmens, Stanford CA USA
- Adaptive designs to accelerate drug development
  Andy Grieve, Sandwich UK

Session IV: Regulatory perspectives

Chairman: *Lawrence J. Lesko*, Rockville MD USA

- Contribution of exposure response relationship to assessment of effectiveness and safety
  Robert Meyer, Rockville MD USA
- Examples of using exposure response relationship and regulatory decisions to support labeling
  Lawrence J. Lesko, Rockville MD USA
- The European perspective
  Gunnar Alván, Uppsala SE

Session V: Integration of preclinical exposure-response information for clinical dose finding

Chariman: *Carl C. Peck*, Washington DC USA

- Integrating preclinical data into clinical phases of drug development
  Hartmut C. Derendorf, Gainsville FL USA
- Is preclinical pharmacokinetics alone sufficient to guide clinical dose selection?
  Johan Gabrielsson, Södertälje SE
- Identification and application of preclinical markers for safety assessment
  Mark C. Rogge, Seattle WA USA

Session VI: Integrating exposure response into clinical development

Chairman: *Donald R. Stanski*, Stanford CA USA

- Mechanism-based PK/PD modelling for prediction of exposure response
  Meindert Danhof, Leiden NL
- Exposure response relationships in modelling and simulation: Industry perspective
  Peter A. Milligan, Sandwich UK
- Integrated exposure response models and quantitative decision-making in clinical development
  Russell Wada, Mountain View CA USA

Session VII: Biomarkers and dose adjustment

Chairman: *William Jenkins*, Basel CH

- Biomarker panels versus single biomarkers to predict clinical endpoints
  TBA
- A standardised approach for using exposure/response relationships to adjust doses in special populations
  Peter Lee, Rockville MD USA
- Minimum cassette of dose-response assessment
  John Urquhart, Maastricht NL
- Setting the stage for break-out sessions 1-6
  Fritz R. Bühler, Basel CH

Session VIII:

- Integration session
- Integrated exposure response assessment
- Opportunities and limitations of pharmacogenetics in drug development
- Biomarkers and their validation
- How could drug development be reengineered in principle?
- Proof of concept
- New study design methodologies

Conclusions and closing

- What have we learned of the present Conference?
  Don Stanski, Stanford CA USA
- Needs for the future
  Fritz R. Bühler, Basel Basel CH
- Concluding remarks
  Ole J. Bjerrum, Copenhagen DK

Conference Leadership

Art Atkinson (MD USA), *Ole J. Bjerrum* (Co-Chair, DK), *Fritz R. Bühler* (Co-Chair, CH), *Meindert Danhof* (NL), *Anders Grahnén* (SE), *William Jenkins* (CH), *Larry Lesko* (MD USA), *Carl C. Peck* (DC USA), *Paul Rolan* (UK), *Malcolm Rowland* (UK) and *Don Stanski* (CA USA).

More information

Contact the EUFEPS Secretariat or the ECPM Secretariat for a copy of the Second Announcement, including registration form and hotel reservation form etc. Also, inform your colleagues about this important Conference.

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