EUFEPS

NEWS Letter

European Federation for Pharmaceutical Sciences March 2001 Vol 10 No1

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

Editors

Dominique Duchêne
Jean-Yves Legendre

Lay-out

Camilla Boquist/Lådan & Co

EDITORIAL

New attractive research initiative

Based on an open call of the Quality of Life Programme of the EU 5th Framework Programme for Research and Technological Development, EUFEPS, recently, initiated and organised a consortium on "Faster development of new, safe drugs in Europe using functional genomics in drug dispo - sition, metabolism and toxicity". In this article, the progress, as well as future steps are presented.

Background

On November 15, 2000, the European Commission issued a call for "Expressions of interest for topics concerning Integrated Projects in Functional Genomics relating to Human Health", with a February 9, 2001, deadline. Suggested topics should exploit multidisciplinary approaches, as well as advance the development and application of new methods and technologies.

Each project (worth up to 10 million Euro) should cluster a number of Research, Technological Development and co-ordination projects, and host 150 man-years of fellowships. In addition, the integrated projects should perform groundbreaking research. The fellowships would provide training for young researchers at Europe's top centres in the field, both in academia and in industry.

Emerging consortium

Based on this information the EUFEPS Membership was invited to suggest research topics and to report their interest to join a consortium for a so called "Integrated Project". Many did, and a series of teleconferences were scheduled for further discussion. Also, the following centre heads signed a "letter of intent" for further collaboration:

University of Vienna, AU – Prof. Christian Noe
University of Ghent, BE – Prof. Stefaan C. De Smedt
Royal Danish School of Pharmacy, DK – Prof. Sven Frøkjær
University of Cologne, DE – Prof. Uwe Fuhr
Saarland University, DE – Prof. Claus-Michael Lehr
University of Oulu, FIN – Prof. Olavi Pelkonen
Univeristy of Parma, IT – Prof. Paolo Colombo
Leiden/Amsterdam Centre for Drug Research (LACDR), NL – Prof. Gerard Mulder
Karolinska Institue, Solna, SE – Prof. Magnus Ingelman-Sundberg
University of Manchester, UK – Prof. David Clarke

In several of the countries represented, sub centres associate to the major contractors, including regulatory agencies in Austria, Denmark, Finland, Italy and Sweden. Industrial partners include GlaxoSmithKline, Janssen, and Novo Nordisk.

Research focus and aim

To fulfil the criteria of the call regarding functional genomics, combined with the drug development process, it was agreed to focus on the protein aspects of the absorption, metabolism, toxicity and disposition of drugs. Accordingly the application got the following objectives:

- To map and describe the post-genomic molecular mechanisms that determine the destiny of a given drug within the body, emphasising the link between the *in vitro* and *in vivo* situation for prediction purposes;

Continued on page 2

Letter from the President:

Dear Colleagues,

For the third time, I have the pleasure of addressing you through our Newsletter. For the third time, I would like to insist on the necessity of a close collaboration between EUFEPS and its membership. This collaboration has to be reciprocal: from EUFEPS towards its members, from its members (member societies and individual members) towards EUFEPS.

Several times this year, we have tried to involve our members in a variety of our activities. First, we sent all our members a two-dimensional matrix with scientific disciplines and research and development processes, asking them to locate themselves, in order to know them better and to be able to work specifically with some of them on scientific topics. Some answers are still missing, and if you recognise yourself among these late comers, please hurry up! The second time was in the organisation of our 10th Anniversary which will be celebrated in September in Strasbourg (France) where EUFEPS was created in 1991. On this occasion we will organise a conference on the "Rational Design of Drug Materials and Drug Delivery Systems", which will take place in the European Parliament on September 20-21, 2001. We will associate all our member societies with this event, by inviting one of their representative to attend the Conference, and by printing the logo of their association on the final programme. We do hope that all our members will decide that it is their duty to participate in this Conference, not by only attending, but by also presenting posters of their research work, and by motivating their colleagues in such a manner that the Strasbourg event will really be a scientific festival for EUFEPS 10th Anniversary.

This issue of our Newsletter was created in close collaboration with one of our Member Societies. The Association de Pharmacie Galénique Industrielle (APGI) accepted to help, and we really hope that, in the near future, other Member Societies will write to us to volunteer to be our partner in spreading information.

I look forward to seeing most of you in Strasbourg for our Anniversary,

Prof. Dominique Duchêne
EUFEPS President

Continued from page 1

- To define the genetic polymorphisms of the proteins involved in transport and bio transformation for better prediction of differences in drug efficacy in individual patients;
- To study toxicogenomic responses *in vitro* and *in vivo* for better prediction of toxicity and improved drug safety;
- To exploit as soon as possible the results, methodologies and techniques used in drug development by further cultivating the established inter-disciplinary network between academia, regulatory authorities and industry;
- To disseminate know-how to all interested parties by: pan-European collaboration involving students, researchers and agency officials; student mobility and specialised training on existing platforms, such as the university network ULLA, and pan-European organisations, including the European Federation for Pharmaceutical Sciences (EUFEPS), European Association for Clinical Pharmacology and Therapeutics (EACPT), European Agency for the Evaluation of Medicinal products (EMEA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The cost for fulfilling these objectives is expected to amount a total of 7.5 million Euro.

Secretarial hub

EUFEPS has made an offer that its Secretariat would be available to administratively serve the consortium, including on accounting and other financial matters. The integration aspect, as well as the expected emphasis on the training and education aspects, call for an effective management and administration. The consortium leadership could then concentrate on the scientific side.

Additional motive

Another reason for the EUFEPS involvement in the application procedure for an EU Integrated Project, is the indirect support such an application would give the New Safe Medicines Faster initiative. By responding to the call, with a proposal related to the drug development process, it sends a clear message to the Commission that European researchers are ready to go for New Safe Medicines Faster topics, if they be incorporated in the EU 6th Framework Programme for Research and Technological Development for 2002-2006. The participation of five regulatory agencies in the consortium supports the urgency which was clearly communicated in the New Safe Medicines Faster Report from the March 2000 Brussels Workshop (see article on page 6 and the EUFEPS Website: www.eufeps.org).

A final round

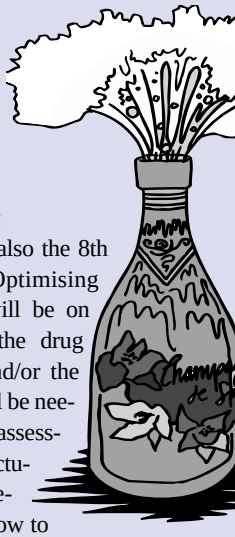
Today, we know that the competition for being picked for the final application round will be fierce. As many as 80 submissions have been received in Brussels, in the first round. Out of those 5 – 8 topics will be picked for the conclusive call. After this, a final round will follow. For a current update on this EUFEPS endeavour, also consult the EUFEPS Website at: www.eufeps.org

Investment for the future

Even if we would not succeed to get our topic picked for the definitive call, the networking that has taken place with the present consortium partners will provide a flying start for the first call of the EU 2002-2006 Framework Programme for Research and Technological Development. Certainly, we here expect to see research emerge with focus on drug development issues.

Prof. Ole J. Bjerrum
EUFEPS Vice-President

EUFEPS´ Decennial Anniversary Conference



Scope and aim

In this Conference, which is also the 8th EUFEPS Conference on Optimising Drug Development, focus will be on how to select and design the drug material, the formulations and/or the drug delivery systems that will be needed for the developability assessment (bioavailability, manufacturability, stability) of new chemical entities, as well as on how to conduct the studies from lead identification to "first in man". First day sessions will be

EXECUTIVE SUMMARY

March 2001

The Executive Committee met on November 11-12, 2000, in Basel, Switzerland, in conjunction with the 7th EUFEPS Conference on Optimising Drug Development, and again on February 24-25, 2001, in Frankfurt, Germany, at the occasion of the 3rd European Graduate Students Meeting. At the latter of these two events, the Executive Committee also met and exchanged views with Prof. H. Timmerman (President) and Dr. E. Differding (Secretary General) of the European Federation for Medicinal Chemistry.

Membership

With the *Portuguese Society of Pharmaceutical Sciences* on board, the number of Member Societies increased to 25, representing 23 European countries, by the end of the year 2000. With this, the European north-south balance in the EUFEPS membership is further improved. The number of Individual Members is well past 500, while the Corporate Membership fluctuates, still around a negative slope. The long planned Membership Committee has to come off the ground. There is quite a bit of competition on the market, and a campaign for more supporting organisations is clearly needed. In the year 2000, the total revenues from the Membership came out about EUR 3000 short of what was budgeted (c. f. below).

Finance

The expenditures for 2000 ended up considerably above the revenues. A preliminary net loss for the year 2000, is calculated to about EUR 30 000, despite the fact that also the revenues were well above budget, with about EUR 10 000. Contributions from Congresses were above budget. On the expense side pronounced negative deviations are seen in costs for personnel, for launching the EUFEPS Website, and in costs associated with the Council Meeting, including the Open Forum. Unsatisfactorily, we also had temporary problems with the cash-flow, mainly because of delayed contributions from the European Commission (due to reorganisation of the Commission) regarding the New and Safe Medicines Faster Workshop, held in Brussels in March 2000. Also, expenses amounting to EUR 20 000 attributed to activities to be undertaken in the year 2001, was prepaid already in late 2000.

EU matters

Concerning the New Safe Medicines Faster (NSMF) Project, the promoting letter including the draft letter to be finalised, which were sent out to the Member Societies, have in several countries now been forwarded to governments and other bodies. Promotion is needed also at the level of the European Parliament. The first Position Paper, the report from the Brussels workshop and other pertinent documents are posted on the EUFEPS Website. A call for the interest in participating in an integrated project within a programme on Functional Genomics relating to Human Health was circulated by the end of 2000 and met a good response (see Editorial, on pages 1-2). If the theme agreed on – *Functional Genomics for Medicines development: Drug Disposition, Metabolism and Toxicity* – will be among those finally selected by the Commission, the intention is that EUFEPS would establish a hub, providing secretarial support.

Congresses and conferences

The *7th EUFEPS Conference on Optimising Drug Development: Strategies to Assess Drug Metabolism/Transport Interaction Potential – Towards a Consensus* on November 13-15, 2000, turned out to be a great success, like the previous Basel conferences. For the outcome, see EUFEPS Website.

Although the series of *European Graduate Students Meeting, this year highlighted by the 3rd one*, on February 23-25, 2000, in Frankfurt, attracts an increasing number of graduate students from outside Germany, much more of a "faculty driven participation" would be welcome.

The organisation of the *World Conference on Drug Absorption and Drug Delivery* in Copenhagen, June 18-20, 2001, is well on its way, as is the Conference on *Rational Design of Drug Materials and Drug Delivery Systems*, on September 20-21, 2001, in Strasbourg, France. Also, the Conference on the *Use of Biomarkers: From Drug Discovery through Clinical Practice*, and the frames for the *7th European Congress of Pharmaceutical Science (EUFEPS 2002)*, on October 21-23, 2002, in Stockholm, Sweden, have been set.

Council and Decennial Anniversary

The Conference on *Rational Design of Drug Materials and Drug Delivery Systems* (see left), which will take place on the premises of the European Parliament, will according to plan be followed by the official EUFEPS´ Decennial Anniversary and "Gala Cocktail". The 2001 Open Forum and Council Meeting will be held in Hotel Sofitel, on Saturday, September 22, 2001, in Strasbourg. They will be followed by the Council Dinner, which will take place outside of Strasbourg.

Next meeting

The next Executive Committee meeting is planned for June 2001 in Copenhagen, in conjunction with the *World Conference on Drug Absorption and Drug Delivery* (see above).

Prof. Björn Lindeke
Secretary-General and Treasurer

Rational Design of Drug Materials and Drug Delivery Systems

September 20–21 • 2001 • European Parliament • Strasbourg • France

on "standard development", i.e. the materials design approach, and the second day will concentrate on "non-standard development" of drug candidates, i.e. the drug delivery systems design approach. The Conference will end with the EUFEPS Decennial Anniversary, including a Gala Cocktail.

Call for abstracts

Scientific contributions, as posters, relating to any aspect of drug material and drug delivery will be welcome. Submit the abstract to the EUFEPS Secretariat (see below), before July 15, 2001.

Additional information

For information on the preliminary programme, editorial instructions for abstracts, delegate registration, hotel accommodation etc., consult the EUFEPS Website:
www.eufeps.org
or contact Maria Norrlander
EUFEPS Secretariat
PO Box 1136
SE-111 81 Stockholm, Sweden
Phone +46 8 7235000
Fax +46 8 4113217
Email conferences@eufeps.org

Photo: Dominique Duchêne

From left to right: Michel Vert, Grégoire Schwach, Gillian Barratt, Maria-Teresa Peracchia, Maria Jose Alonso, Paolo Colombo, Per Artursson and Nicholas Peppas.

New trends in polymers
for oral and parenteral administration: From design to receptors

GTRV (Groupe Thématique de Recherche sur les Vecteurs), EUFEPS (European Federation for Pharmaceutical Sciences) and APGI (Association de Pharmacie Galénique Industrielle) held a jointly organised symposium entitled: "New Trends in Polymers for Oral and Parenteral Administration. From Design to Receptors", on March 12-13, 2001, in Paris, France. Approximately 170 delegates were present. The scientific programme included 17 invited lectures from internationally acclaimed speakers and over 50 poster presentations.

Polymer design

The first session was dedicated to polymer design for drug delivery. *Michel Vert* (Montpellier) presented a variety of polymers suitable for this application, which can degrade to yield metabolic intermediates. While the poly(lactide) and poly(lactide-co-glycolide) polymers are well known, they lack reactive side chains for attaching drugs or targeting moieties. Poly(malate) or poly(lysine-co-citramide) could be useful alternatives. Polymerisation of serine by ester linkages yields a polyelectrolyte with pendant amino group which has potential for nucleic acid delivery. Poly(caprolactone) is very slowly degraded in the absence of microorganisms but can be functionalised with carboxyl groups to become more biodegradable.

Nicholas Peppas (West Lafayette) spoke about stimuli-sensitive polymers and in particular polymers which can be used to prepare hydrogels that swell or contract in response to changes in the environment such as temperature and pH variations, thus controlling drug release. For example, short poly(ethylene glycol) chains grafted onto poly (methyl metacrylate) undergo pH-dependant complexation.

Alexander Florence (London) described the drug delivery potential of dendrimers. These branched polymers provide small colloidal systems with low polydispersity which are more stable than micelles. Dendrimers based on lysine or ornithine cores with a lipophilic or an ionic surface have been synthesised. Cationic dendrimers or dendrons (partial dendrimers) have potential for gene delivery. Partial dendrimers could be used to modify the surface of nanoparticles. Although some toxicity and biodegradability issues are not yet resolved, the considerable variety of possible structures gives dendrimers potential as drug delivery systems.

Gérard Riess (Mulhouse) talked about amphiphilic copolymers which could be used to form micelles. In particular, he described block copolymers in which the hydrophilic segment was poly(ethylene glycol). Since the critical micellar concentration of such polymers is of the order of milligrams per litre, very stable micelles with no exchange of monomers could be formed. Micelle stability can be monitored by including a fluorescent group at the interface between the hydrophobic and hydrophilic blocks. Some triblock copolymers for micelle formation were also described.

Paul Neumann Award

At the end of this session, the prize awarded by the Fondation Paul Neumann and the APGI for an outstanding PhD thesis in the field of Pharmaceutical Technology was awarded to *Karine Andrieux* (Châtenay-Malabry) for her work aimed at elucidating the mechanism of liposome solubilisation by bile salts.

Polymers for specific delivery

The second session of the Symposium dealt with modified polymers for specific drug delivery. Firstly, *Jindrich Kopecek* (Salt Lake City) gave a review of work from his laboratory concerning water-soluble polymers for the delivery of anti-cancer drugs. The active agent is linked to the polymer by a labile spacer; for example, a peptide which can be cleaved by lysosomal cathepsin. The conjugate can be targeted by a site-specific moiety such as a Fab' fragment or a smaller epitope. Use of the TAT sequence can lead to intracytoplasmic delivery.

Colonic delivery systems were described by *Abraham Rubinstein* (Jerusalem). Guar gum can be used to prepare hydrogels which are specifically degraded by enzymes in the colonic flora. Cationisation of proteins (for

example superoxide dismutase) increases their interaction with the colonic epithelium. Specific targeting to colonic adenoma cell lines can be achieved with galactose moieties.

The theme of polysaccharides for delivery to tumour cells was continued by the next speaker, *Claudia Gervalas* (Villetaneuse). Many naturally occurring polysaccharides bind to tumour cells and may possess anti-proliferative or immunomodulating activity. In the speaker's laboratory the anti-tumoral activity of substituted dextrans is being screened. Certain derivatives show cytotoxicity against breast carcinoma and melanoma cell lines. In a nude mouse model, synergy was observed between one of these polymers and sodium phenyl acetate, a differentiating agent.

In the final presentation of the day, *Patrick Couvreur* (Châtenay-Malabry) spoke about the interactions between cancer cells and polymers in the form of nanoparticles. When the cell line is capable of endocytosis, nanoparticle-associated drug may be internalised by this process whereas the free drug does not penetrate (for example, the case of oligonucleotides). On the other hand, drug trafficking may be altered even with non endocytic cells, as has been shown for doxorubicin-loaded poly(alkylcyanoacrylate) nanoparticles and multi-drug resistant cancer cells. The adsorption of nanoparticles on the cell membrane and the effect of polymer degradable products promote drug accumulation and reduce efflux. Uptake of nanoparticles by macrophages also plays a role in the anti-tumoral activity by provided a local reservoir of drug. The covalent coupling of folic acid to the surface of pegylated nanoparticles allows specific targeting to tumour cells expressing the folate receptor.

Polymers in formulation design

On the second day, the third session was devoted to polymers in formulation design. *Paolo Colombo* (Parma) discussed hydrophilic polymers for matrix systems with particular emphasis on preparing "smart" tablets. He showed how polymer swelling to form a gel and gel erosion act together to determine drug release profiles. The type of particle coating, permeable to water or not, can also modify the release profiles.

Michael Dittgen (Jena) gave a comprehensive review of acrylic polymers for controlled release. An important property of these polymers is their pH sensitivity. Hydrogen bonding or cross-linking between chains can also affect the swelling rate and drug release. Another possibility for controlled release would be to bind the drug covalently to the polymer. Prof. Dittgen presented examples of applications of these systems for transport across the oral mucosa (bioadhesive devices), by the gastrointestinal tract (coated tablets) and by the parenteral route.

Continuing on a similar theme, *Roland Bodmeier* (Berlin) discussed coating of tablets for extended release. He limited his review to aqueous polymer dispersions which dry to form a film. Different factors which will determine the release characteristics of the resulting granules are the presence of a plasticiser, the pH sensitivity of the polymer, the extent of curing and whether the granules can be compressed without changing the properties of the coating.

Moving from tablets to parenteral formulations, *Grégoire Schwach* (Geneva) gave a timely account of polymers for implants. Depending on the type of polymer, drug release may be by swelling and diffusion, simple diffusion or after matrix erosion, or by a combination of these mechanisms. While non biodegradable polymers can be used to form hydrogels (as described by Prof. Peppas earlier) biodegradable polymers offer attractive possibilities for controlled release. Different degradation behaviour (bulk or surface erosion) and rates allow various drug release profiles. From a practical point of view, semisolid polymers offer the advantage of being administered in a non invasive way. Thermoreversible gels, which solidify at physiological temperatures, are particularly interesting. Major applications include local treatment of cancer, local antibiotic therapy, delivery of peptide hormones and of larger proteins such as growth factors.

Ruxandra Gref (Châtenay-Malabry) spoke about "pegylated" polymers for "Stealth" nanoparticles. The presence of hydrophilic chains at the surface of colloids allows them to avoid opsonisation and uptake by phagocytic cells after intravenous administration, leading to greatly prolonged circulation times. The best studied polymers for this application are poly(lactide)-poly(ethylene glycol) diblock copolymers. Their properties were discussed as a function of the lengths of the two blocks and the density of poly(ethylene glycol) chains at the surface of the nanoparticles formed from them. In particular, opsonisation was studied by two-dimensional electrophoresis and correlated with uptake by phagocytes. These nanoparticles can entrap lipophilic drugs, as well as proteins such as human serum albumin. Controlled release of encapsulated substances can be obtained.

A specific application of particulate polymeric systems is controlled drug delivery in the brain, as explained by *Jean-Pierre Benoît* (Angers). In this case, biodegradable polymeric microspheres containing a drug are implanted by stereotaxis or in the cavity after surgical removal of a tumour. Two applications were discussed : the use of growth factors (nerve growth factor, glial derived neurotrophic factor) for neurodegenerative diseases and the delivery of 5-fluorouracil to treat residual glioblastoma after operation. This latter application is in clinical trials and some positive responses have already been recorded.

Maria-José Alonso (Santiago de Compostela) reviewed polymeric systems for vaccination purposes. Antigens can be encapsulated in microspheres or nanoparticles for controlled release; the ultimate aim being to develop a "one-shot" vaccine without the need for the patient to return for a booster. However, since most antigens are proteins, care must be taken in the formulation to preserve their antigenic activity during formulation. The double emulsion technique of preparing particles is the most appropriate. As well as intramuscular administration, such systems can be given by mucosal routes, in this case leading to both systemic and mucosal (IgA) immunity. In particular, results were presented showing that a good response to tetanus toxoid can be achieved after intranasal administration to mice of pegylated nanoparticles containing this antigen.

Biological interaction of polymers

A final session covered biological interactions of polymers. Firstly Thomas Kissel (Marburg) discussed the biocompatibility and toxicity of various polymers and described a number of tests using fibroblasts as the target cells which are appropriate to assess these parameters (agar diffusion test, direct contact method, extraction assay).

Per Artursson (Uppsala) reviewed the interactions of modified polymer-based systems with cells, with particular emphasis on the effect of chitosan and polyethylenimine on drug permeability through monolayers of intestinal epithelial cells and on DNA transfection.

The wide variety of different applications for polymers described by the speakers at this meeting and the sophistication of the systems formed from them demonstrate that polymers can no longer be considered as simple excipients but as active parts of many pharmaceutical formulations. This area will undoubtedly expand even further in the 21st century.

Dr Gillian Barratt
President of GTRV

New Safe Medicines Faster

Recent developments

The aim of the launch of the New Safe Medicines Faster (NSMF) EUFEPS initiative, in 2000, was to provide a dedicated focus of the pharmaceutical sciences for the forthcoming Research and Technological Development Framework Programme of the European Community for 2002-2006. In this article, the Project Leader, Prof. Ole J. Bjerrum, reports on the current outcome.

Promotion plan

The promotion plan for the New Safe Medicines Faster Initiative was simple. It should:

1. Involve the European research community, i.e. the European Commission, the European pharmaceutical industry (EFPIA), the academia, and the European regulatory agencies.
2. Deliver, to the Commission, a detailed inventory regarding existing bottlenecks, as well as urgent research topics, methodologies and techniques.
3. Interact with, and support, the Commission during the drafting of the work programme for the forthcoming Framework Programme.
4. In publications, inform key players for feedback to the Commission, such as the European research and science organisations, national governmental bodies, Members of the European Parliament and patient organisations.

The activities under item 1 were achieved through the publication of and follow-up on the EUFEPS NSMF Position Paper of August 1999. Item 2 was covered by the New Safe Medicines Faster Workshop, organised by EUFEPS with EU support, on March 15-16, 2000, in Brussels, Belgium, and through the publication of the Workshop Report of July 1, 2000. The remaining two promotion activities are being undertaken, currently, and your continuous support will be needed (see below).

On this occasion, on behalf of EUFEPS, I want to thank those of you who, so far, acted as ambassadeurs for the New Safe Medicines Faster Project, by promoting our initiative in the research and governmental circles of the individual EU member states. I can ensure you that this bottom-up process, indeed, produced feedback to the Commission. In this way, the officers of the Quality of Life Directorate of the Commission have been convinced of the importance and need for support of the pharmaceutical sciences research.

First outline of next programme

Therefore, with great interest, we received a copy of the Commission's first draft of the "Multiannual framework programme 2002-2006 of the European community for research, technological development and demonstration activities aimed at contributing towards the creation of the European research area", in the beginning of March 2001. Did New Safe Medicines Faster appear? No, the exact wording was not included, but there was room nicely made available for the contents of our proposal.

Of the seven research themes that are suggested, by the Commission, currently, theme one, on "Genomics and biotechnology for health", hopefully to be funded with 2000 million Euro, reads as follows:

- Fundamental knowledge and basic tools for functional genomics:
  - gene expression and proteomics
  - structural genomics
  - comparative genomics and population genetics
  - bioinformatics
- Application of knowledge and technologies in the field of genomics and biotechnology for health:
  - technological platforms for the development of new diagnostic, prevention and therapeutic tools
  - support for innovative research in genomics start-up companies
- Application of medical genomics knowledge and technologies in the following fields:
  - combatting cancer, degenerative diseases of the nervous system, cardiovascular diseases and rare diseases
  - combatting resistance to drugs
  - studying human development, the brain and the ageing process.

Photo: Philippe Veldeman

Many discussions will be needed for success.

Input to the work programme

The emphasised bullet points cover the New Safe Medicines Faster initiative, no doubt. In the next edition of the work programme, we hope, however, to see this section of the work programme expanded with the following text:

- Research related to new methodologies and technologies for increasing the overall capacity of the exploratory and human (clinical) drug and vaccine development process, and to making the associated techniques more efficient by increasing their predictability and validity for human use.
- To ensure fast implementation, the research should be conducted together, or in consultation, with regulatory authorities.

Remaining activities

Even for the very optimistic progress, the "battle" has not yet been won. A continuous flux of positive support of expressions will still be needed from you to reach all levels of those involved in the finalising of the 6th Framework Programme. As indicated above, they also include European research and science organisations, such as national research councils, regulatory agencies, national governmental bodies relating to EU matters and issues, Members of the European Parliament, and patient organisations. Therefore, all of you important ambassadeurs, out there, please do not stop putting pressure on the national EU stakeholders, for including the "New Safe Medicines Faster" in the Programme. On EUFEPS Website (www.eufeps.org) you may find material to be used in your promotion campaign.

Finally…

Full steam ahead. The goal is near!

Prof. Ole J. Bjerrum
EUFEPS Vice-President

Particle Size, Characterisation and Surface Conference in Advanced Medicinal Chemistry
May 18-19, 2001, Thessaloniki, Greece
Contact: Prof. P.N. Kourounakis, Aristotelian University of Thessaloniki, School of Pharmacy GR-540 06 Thessaloniki, Greece
Fax +30 31 997622

*

From Design to Realisation in Medicinal Chemistry
May 31 – June 1, 2001, Namur, Belgium
Contact: Ly Differding, Route de Blocry 55 BE-1348 Louvain-la-Neuve, Fax +32 10 459719
Email jfb@ldorganisation.com
Website www.fundp.ac.be/sciences/pharmacie/jfb.htm

*

Chemistry 2000: Promoting Younger Chemists
July 2-4, 2001, London, UK
Contact: Dr Eric Wharton, Place Cottage, 1 The Green, Chilton, Didcot, Oxon OX11 OSD, UK
Fax +44 1235 820686
Email eric@eric-wharton.freeserve.co.uk

*

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

*

World Conference on Drug Absorption and Drug Delivery – Benefiting from the New Biology and Informatics
June 18-20, 2001, Copenhagen, Denmark
Contact: WCDADD c/o DIS Congress Service Copenhagen A/S, 2 C, Herlev Ringvej, DK-2730 Herlev, Denmark, Fax +45 44925050
Email WCDADD@discongress.com
Website www.eufeps.org

*

International Symposium on Positron Emission Tomography (PET) in Drug Development
August 15-19, 2001, Uppsala, Sweden
Contact: Bengt Långström, PET Centre Uppsala, Sweden
Email bengt.langstrom@pet.uu.se
Website kongress@ukkab.se

*

BIO-INTERNATIONAL 2001: Drug Product Quality Assessment – Approaches for Regulatory Harmonisation in South East Asia
August 31-September 2, 2001, Saskatchewan, Canada
Contact: FIP Congresses and Conferences, P.O. Box 8420, NL-2508 AE The Hague The Netherlands, Fax +31 70 3021998
Email monique@fip.nl

*

Heterocyclic Compounds II: Biological Activity, Synthesis and Structure
September 10-12, 2001, Hradec Králové Czech Republic
Contact: SHC, Department of Inorganic & Organic Chemistry, Faculty of Pharmacy, Charles University, Heyrovského 1203, CZ 50005 Hradec Králové, Czech Republic
Fax +420 49 5210002, Email shc@faf.cuni.cz

*

XVIII Scientific Congress of the Polish Pharmaceutical Society
September 20-22, 2001, Poznan, Poland
Contact: XVIII Scientific Congress of the Polish Pharmaceutical Society, Collegium Chemicum, 6 Grunwaldzka street, PL-60-780 Poznan, Poland
Fax +48 61 8656671

*

British Pharmaceutical Conference
September 23-26, 2001, Glasgow, UK
Contact: Ms K. Elder, Room 301 B, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 75820397
Email kelder@rpsgb.org.uk

*

Optimising Drug Development: Rational Design of Drug Materials 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

*

5th International Symposium on the Biological Oxidation of Nitrogen in Organic Molecules
October 4-6, 2001, Munich, Germany
Contact: Bernd Clement, Pharmazeutisches Institut, Gutenbergstraße 76, DE-24118 Kiel Germany. Fax +49 431 8801352
Email bclement@pharmazie.uni-kiel.de
Website www.issx.org

6th International ISSX Meeting
October 7-11, 2001, Munich, Germany
Contact: Congress, Meeting & Event Management, Albert-Rosshaupter-Strasse 65 DE-81369 Munich, Germany
Fax +49 89 54823444, Email issx@i-plan.de
Website www.i-plan.de

*

Optimising Drug Development Use of Biomarkers: from Drug Discovery through Clinical Practice
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

*

Methodological Perspectives in Health Services Research: International PhD Course
January 13-18, 2002, Nyborg (Funen), Denmark
Contact: Prof. Ebba Holme Hansen, Dept of Social Pharmacy, Royal Danish Scool of Pharmacy, Universitetsparken 2, DK-2100 Copenhagen, Denmark, Fax +45 35 306001
Email ehh@dfh.dk

*

Quantitative Approaches to the Evaluation of Health Care Inputs, International PhD Course
April 8-19, 2002, Copenhagen, Denmark
Contact: Prof. Ebba Holme Hansen, Dept of Social Pharmacy, Royal Danish Scool of Pharmacy, Universitetsparken 2, DK-2100 Copenhagen, Denmark, Fax +45 35 306001
Email ehh@dfh.dk

*

Drug Analysis 2002
April 21-25, 2002, Bruges, Belgium
Contact: ORGA-MED Congress Office, Essenestraat 77, BE-1740 Ternat, Belgium
Fax +32 2 5825515
Email orgamed@village.uunet.be

*

EUFEPS 2002: New Safe Medicines Faster
October 21-23, 2002, Stockholm, Sweden
Contact: EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden
Fax +46 8 4113217
Email conferences@eufeps.org
Website www.eufeps.org

*

9th EUFEPS Conference on
Optimising Drug Development: Use of Biomarkers from Drug Discovery through Clinical Practice
December 10–12 • 2001 • Basel Convention Center • Switzerland

Aim and objective
This two and a half day Conference will present and discuss the needs and the latest scientific opportunities to improve the identification of biomarkers in disease and their use in assessing therapeutic interventions during drug development and regulatory decision making, through to clinical practice. As with previous successful EUFEPS Conferences on "human drug development" (Wiesbaden 1998 and Basel in 1999; for reports, see EUFEPS Website: www.eufeps.org), this Conference will be a unique and intensive discussion forum bringing together industrialists, academicians, and regulatory scientists, to identify areas of both agreement on key issues, as well as areas of disagreement, with ways forward toward resolution.

Current sessions
Setting the stage, including outcome of COST B15 meetings on biomarker issues • Anticipated benefits in identifying and using safety and efficacy biomarkers in drug development – from preclinical to end of phase II • Biomarker applications in late drug development and life cycle management: Anticipated benefits and differences in risk acceptance of using a biomarker • Biomarker applications from regulatory review through clinical practice • Where do we go from here?: Reports from break-out sessions and discussion of position statements • Future perspective on biomarkers, drug development and trends in regulations.

Additional information
For reports from previous conferences in the series, as indicated above, information on the preliminary programme, delegate registration, hotel accommodation etc., consult the EUFEPS Website: www.eufeps.org or contact Maria Norrlander, EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Phone +46 8 7235000 Fax +46 8 4113217 Email conferences@eufeps.org

Posttidning B

EUFEPS Newsletter
PO Box 1136
SE–111 81 Stockholm
Sweden

APGI
Association de Pharmacie Galénique Industrielle

APGI involvement

APGI (Association de Pharmacie Galénique Industrielle) is proud to participate in the production of this Newsletter issue, as a joint effort with EUFEPS. We share, indeed, the aim and the commitment of EUFEPS to closely associate the Member Societies with its communication policy. We believe that such collaboration is the starting point of many more such ones, in the future. As a matter of fact, APGI has quite a long history with EUFEPS since it was an observer at the foundation meeting in Strasbourg, in 1991, and joined the Federation in 1992.

APGI interests

APGI was founded in Paris in 1964, and it has, over the years, developed into one of the most important associations in the field of pharmaceutical sciences, in France as well as in Europe. Our association has now roughly 400 members representing from about 30 countries. APGI's interests include pharmaceutical technology, drug delivery, biopharmacy and cosmetics. Our main mission is to promote the research and to facilitate the dissemination of the information, in these areas, among the people from academics, industry or governmental agencies.

APGI activities

To do so, APGI shares, with the French SFSTP (Société Française des Sciences et Techniques Pharmaceutiques), the publication of an international scientific journal: STP Pharma Sciences, and also provides its membership with professional information appearing in the quarterly Gazette de l'APGI. With the same objective, APGI organises all sorts of professional meetings, both in France and abroad. Some of its scientific symposia are co-organised with scientific associations or societies, such as: the Swedish Academy of Pharmaceutical Sciences, the Controlled Release Society, the Türk Farmasötik Teknoloji Arastırmalacıları Dernegi, the Nagai Foundation, the Chinese Pharmaceutical Association, the Royal Pharmaceutical Society of Great Britain, the Sociedade Brasileira de Tecnologia Farmacêutica, and Lomonosov Moscow State University. They take place either in France (Paris) or abroad, e.g. Stockholm, Istanbul, Beijing, Moscow, and Recife. The most well known event is, undoubtedly, the World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology. This meeting was co-organized by APGI and APV (Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik), in 1995 in Budapest, in 1998 in Paris, and in 2000 in Berlin. The next World Meeting will take place in Florence, Italy, in April 2002, and it will be a joint effort between APGI, APV and ADRITELF (Associazione Docenti e Ricercatori Italiani di Tecnologie e Legislazione Farmaceutiche), under the auspices of EUFEPS and FIP.

APGI information

On the behalf of APGI, I do hope to have the pleasure to welcome you at this world-class event. Please feel also free to navigate on the net to: www.apgi.org to get more information on our association. APGI members and myself look forward to meeting you soon.

Jean-Yves Legendre, PhD, APGI President