EUFEPS

NEWS Letter

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Address
EUFEPS Secretariat
P.O. Box 1136
SE-111 81 Stockholm, Sweden
Phone: +46 8 7235000
Fax: +46 8 4113217
Email: secretariat@eufeps.se

Editor
Hans H. Lindén

Lay-out
Liza Peterzon

EDITORIAL

Let's publish, inform and communicate

Professor Dominique Duchêne
Université Paris-Sud, France

In the last issue of the EUFEPS Newsletter, the expanded Executive Committee was introduced to you with a main task assigned to each of its members. For my part, I was nominated for publications and information.

This is a rather complex responsibility, because even if it is easy to know what EUFEPS publications are, it is not so easy to know what exactly are the limits of information.

However, I shall try to give you an idea of our activities in these fields.

Dominique Duchêne

Publications

The EUFEPS international publication organ is the *European Journal of Pharmaceutical Sciences*. For eight years this journal has represented our scientific flag all over the world. The authors come from about 30 different countries: Austria, Belgium, Bosnia and Herzegovina, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Norway, Poland, Saudi Arabia, Singapore, Slovenia, South Africa, Spain, Sweden, Switzerland, Thailand, The Netherlands, Turkey, the United Kingdom, and the United States. Subscriptions for 1999 were 56% from Europe, 23% from the Americas, 17% from Asia and Australia, and 4% from the rest of the world.

The scientific quality of the journal was under the responsibility of its editor-in-chief: Hans E. Junginger from Leiden for six years, and is now the responsibility of Per Artursson from Uppsala. Both Hans and Per are renowned scientists, Hans for his work on peptide delivery and absorption of peptides by means of penetration enhancers through various mucosa and cell membranes and more especially on the role of chitosan, and Per for his work on the mechanisms of drug absorption through the gastro-intestinal pathway, with special attention to Caco-2 cell intercations. Per has with him a group of co-editors who are a guarantee of the reviewers' authority and the quality of published papers.

The impact factor, which represents how frequently a journal is referenced in the scientific literature, is one of the keys to receiving papers from the best scientists. It is presently 1.103, and this is more than honourable for a nine-year-old journal, especially if we consider that the best journal in the same field has 2.530. The objective is to increase this impact factor as much as possible. This can be achieved with a permanent increase in the quality of published papers, but also with a discipline to be observed by all the scientists who are friends of EUFEPS. This discipline is very simple: "When you write a paper, do not forget to cite papers published by the European Journal of Pharmaceutical Sciences". If you feel concerned by the future of EUFEPS and pharmaceutical sciences in Europe, you must be very attentive to this and you can be very helpful.

Another issue is that there are still other journals in Europe competing with the European Journal of Pharmaceutical Sciences. I initiated discussions to consider the possibility of merging with two of the other main European journals. However, such a merger does not depend only on the will of scientists, but also on the goodwill of the publishers. So, let's wait and see.

Continued on page 2

April 20, 2000, is the deadline for announcements and manuscripts for the next issue of the EUFEPS Newsletter

EUFEPS publishes the *abstracts of the European Congress of Pharmaceutical Sciences* in special issues of the European Journal of Pharmaceutical Sciences. Such a policy allows international dissemination of all the contributions presented at the Congress, and, consequently, it brings European research groups to the attention of the international scientific community.

Finally, in my opinion, it should be considered a duty for EUFEPS to initiate the writing of *books on pharmaceutical sciences* by the best European and international scientists on up-to-date pharmaceutical science topics, and to publish them under the aegis of EUFEPS.

Information

EUFEPS has two channels to inform and communicate with its members: the website, which will be established, shortly, and the EUFEPS Newsletter.

The *website* is presently the object of intensive attention and work by Hans H. Lindén. It will give everybody easy access to EUFEPS activities, and it is expected that it will become a discussion forum for all EUFEPS members.

The *EUFEPS Newsletter* is a very clear and concise means of informing the members of EUFEPS of recent activities or projects. It is also a means for the EUFEPS member societies to let others know about their own activities. For example, we recently had a report on the Helsinki University Congress of Drug Research and on the 6th Intermediate Level Workshop on PK/PD, organised in Cambridge by the Royal Pharmaceutical Society of Great Britain and the Swedish Academy of Pharmaceutical Sciences.

It is a pity that we do not receive more direct information about the activities of our member societies. In fact, EUFEPS would like its member societies to benefit from their membership. This means that the EUFEPS Newsletter could be a forum for communication between EUFEPS member societies, in which they could introduce themselves, describe their activities, and propose cooperation on scientific topics or events to other members.

As it is intended to publish the EUFEPS Newsletter on the website, this type of information would be easily and widely available.

My personal remark is that, for the moment, we do not behave as a true partner of EUFEPS. This is not the fault of EUFEPS; this is because we do not demonstrate enough strength in our desire for Europeanisation.

We are within an internationally recognised European federation. This is a plus for each of us if we want to merit it and if we want to share it.

Conclusion

You can probably guess what my conclusion will be.

We, EUFEPS members, must be more interdependent: with each other and with EUFEPS. Then we will be stronger, we will be what we should be. We will have participated in the recognition of the European pharmaceutical sciences, not only with respect to the scientists, but also with respect to our health authorities. We will have truly worked for the Pharmaceutical Sciences.

6th European Congress of Pharmaceutical Sciences

September 16-19 • 2000 • Budapest • Hungary

This 6th European Congress of Pharmaceutical Sciences follows an eight year tradition, and it is organised in close co-operation with the Pharmaceutical Societies of Europe, and the International Pharmaceutical Excipients Council.

Original work

Original work covering industrial and academic advances in all areas related to drug development and product optimisation, such as synthetic and analytical chemistry, pharmacy, pharmacology, biopharmaceutics and technology, will be presented at this Congress.

Congress website

For the Scientific Programme, including invited lectures from distinguished international scientists, and a special session with IPEC, as well as Mini-Symposia and Discussion Fora, posters will play a central role, as they present new achievements in pharmaceutical sciences and offer the possibility of direct contact between practitioners and innovators. The Scientific Programme will be supported by an Exhibition of technical instruments and products for the pharmaceutical sciences.

Also, for the attractive social programme and any other information on the Congress, consult the Congress Website: www.pharmweb.net/conference/eufeps2000.html

Second circular

For a personal copy of this, contact the EUFEPS 2000 Congress Secretariat, P.O. Box 11, HU-2011 Budakalász, Hungary
Tel +36 26 340203 or 343166
Fax +36 26 343195 or +36 26 340426
Email eufeps2000@mail.matav.hu
or rimp@mail.matav.hu

Budapest Convention Center

EXECUTIVE SUMMARY

February 2000

The last meeting of the Executive Committee, before the turn of the Millennium, took place on November 28 - 29 in a somewhat brisk and wintry but quite sunny Basel, Switzerland. The Committee met at the Swissôtel, in conjunction with the 6th EUFEPS Conference on Optimising Drug Development: Streamlining Proof of Concept. The programme of the Conference was rated as excellent with a high quality profile, and the attendance must be regarded as satisfactory. For a special report from the Conference, see pages 4-5.

Membership

Following the 1999 Council Meeting, at which *APV* joined EUFEPS, and the subsequent discontinuation of the memberships by the *French Academy of Pharmaceutical Sciences and the Technical Industrial Pharmacists and Pharmaceutical Scientists Association of Ireland (TIPPSA)*, EUFEPS comprises 24 Member Societies in 21 European Countries. Despite some turn over, the representation thus is similar to what was seen after the 1998 Council Meeting. The Individual Membership has now reached well above 500 persons.

Newsletter and Website

Major discussions within the Executive Committee have been devoted to the areas of functional responsibilities as previously outlined (see the December 1999 issue of the Newsletter). For example, we should aim at an improvement of the *EUFEPS Newsletter.* One problem is, however, to get people to contribute to it. It is realised that when EUFEPS will have a working website in place, this could alter the role of the Newsletter. Prof. D. Duchêne has declared a willingness to take over the role as Editor of the Newsletter. This will allow Hans H. Lindén more time to spend on the establishment of the EUFEPS Website, with the help of PharmWeb of Manchester, UK, commissioned to design and be the technical service provider.

Industrial relations and new medicines

Actions undertaken by *CIR* are aimed at fostering an open dialogue between industry on the one hand and academia as well regulatory bodies on the other. Also, a particular focus is on scientific training needs, and how to approach and get an involvement with the EU. Another important issue is the promotion of scientific groups within EUFEPS. There is a need to identify the key players in the pharmaceutical sciences training arena, with the clear distinction that EUFEPS focuses on postgraduate and continuing education in the pharmaceutical sciences. With the proposal on *New Safe Medicines Faster*, aiming at a Key Action of the European Union's 6th RTD Framework Programme, we have now been successful, as it has awaken the interest of the EU Commission. A Workshop for further development of the ideas will be held on March 15-16, 2000, in Brussels, partly funded by the European Commission. Also, the question has been raised whether there is a future need for a EUFEPS Committee on Pharmaceutical Policies (CPP), or should we rather set up a Committee for "Regulatory Sciences"?

Congresses and Conferences

It has been repeated that EUFEPS must have a better control of its own congresses. Hopefully, this will ultimately materialise. Less than 50 per cent of the participants follow the Congress from one occasion to another, which means that the EUFEPS members do not identify themselves as yet with what should be their Congress. We aim to change this situation in the future.

Regarding conferences many of these, especially the annual "Nuremberg Series", have been highly successful. Here, EUFEPS has taken an innovative and leadership role, attracting the attention of senior scientists both in regulatory agencies and in industry.

The Second Circular for the *6th European Congress of Pharmaceutical Sciences* on September 16-19, 2000, in Budapest is now being distributed. For the *7th European Congress of Pharmaceutical Sciences*, in 2002, in Stockholm, the dates have been set to October 21-23, and the venue will be the Stockholm International Fair, located in Älvsjö, South of Stockholm. Concerning the *8th European Congress of Pharmaceutical Sciences*, in 2004, in France, the date and venue still need to be fixed. The set up of the *International Conference on Drug Absorption and Delivery*, in June 2001, proceeds according to plan.

Liaisons

With regard to liaisons these must be seen to be of mutual benefit to both EUFEPS and the other organisation. General rules for lines of communication must be developed. They should comprise the appointment of *Liaison Officers* as contact points to the Executive Committee or applicable subcommittees. When courses and symposia are jointly organised, letters of understanding should be signed and financial models be agreed upon.

FIP's Board of Pharmaceutical Sciences is moving towards greater independence (e.g. separate conferences/congresses). EUFEPS is supportive of this development, and EUFEPS and FIP should collaborate on global issues.

Next meeting

The next Executive Committee meeting will take place in Brussels, March 17-18, 2000, in conjunction with the *Workshop on New Safe Medicines Faster*. The subsequent Executive Committee Meeting is planned for Leiden, The Netherlands, on May 20-21, 2000.

Björn Lindeke, Professor
Secretary-General & Treasurer

Scheele Prize 2000

The 2000 Scheele Prize winner is Prof. Douwe D. Breimer, Leiden, The Netherlands. By this Prof. Breimer's outstanding contribution to the field of pharmaceutical science at large, including to the foundation of EUFEPS and ULLA, and his pioneer research in pharmacokinetics and pharmacodynamics, are recognised.

Professor Breimer will receive the Scheele Prize 2000 at the Swedish Academy of Pharmaceutical Sciences Annual Congress, on October 11, 2000.

The Scheele Prize winner is awarded a special Diploma, The Scheele Medal and a Prize Sum of SEK 100,000.

Conference Report

Optimising Drug Development: Streamlining Proof of Concept (POC)

November 30 - December 2 • 1999

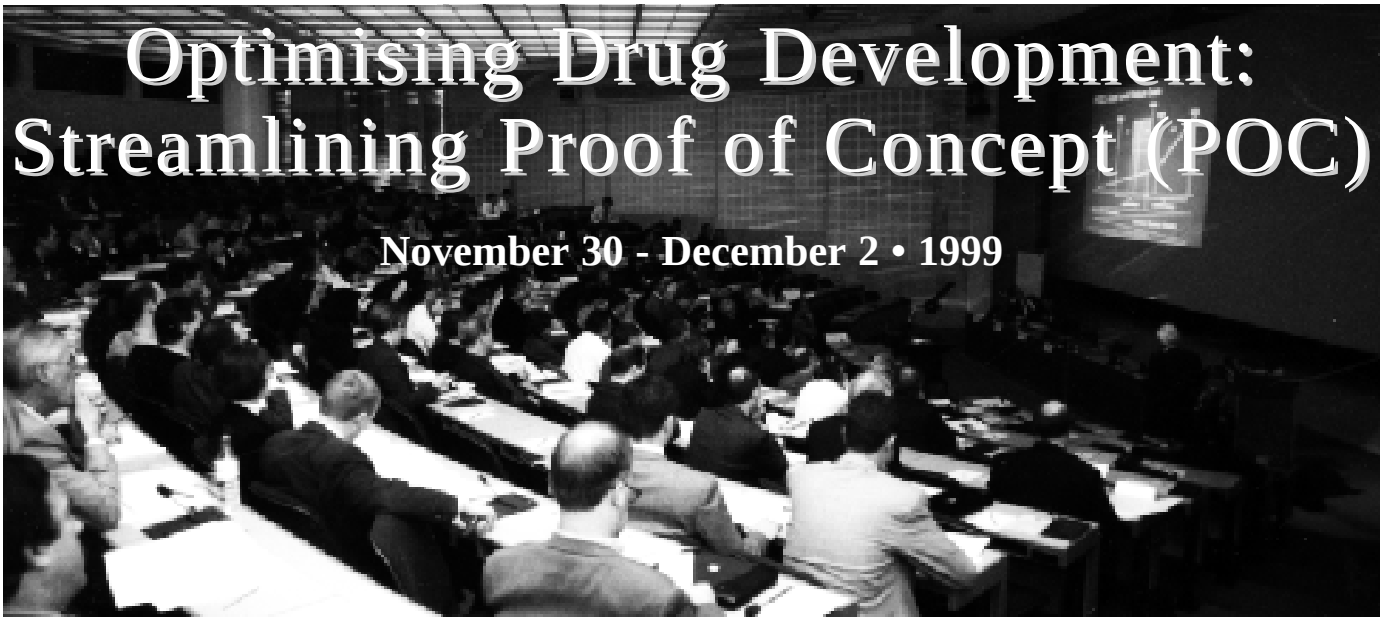


Photo: Basilisk

For the sixth time, pharmaceutical scientist from all over the world gathered under EUFEPS leadership to discuss scientific topics related to drug development, this time to address streamlining of proof of concept for the optimisation of the dug development process. This was the second conference specifically devoted to optimising drug development, the first one held in 1998 (Wiesbaden) related to "Fast Tracking into Human". The Conference was held at the Basel Convention Center (November 30 – December 2) under the Chair of Professor Fritz Bühler (Director of the European Centre of Pharmaceutical Medicine – ECPM).

Important topic

The importance of the subject matter was emphasised trough the distinguished list of co-sponsors for this Conference, including: the European Medicines Evaluation Agency (EMEA), the US Food and Drug Administration (FDA), The European Association for Clinical Pharmacology and Therapeutics (EACPT), The American Association of Pharmaceutical Scientists (AAPS), The American Society for Clinical Pharmacology and Therapeutics (ASCPT), the European Centre of Pharmaceutical Medicine (ECPM), the Leiden/Amsterdam Centre for Drug Research (LACDR), the Centre for Drug Development Sciences, USA (CDDS) and the Tufts Centre for the Study of Drug Development, USA (CSDD).

Conference Programme

The EUFEPS President Professor Malcolm Rowland opened the proceedings by setting the stage for the Conference and giving a summary outcome of the previous one on "Fast Tracking into Human". The meeting was divided into eight (8) major sessions. Breakout sessions associated with the session themes were organised in the evenings. In an extra session, Dr Steve Arlington from PricewaterhouseCoopers, and author of the report "Pharma 2005. Silicon Rally: The race to e-R&D", gave a provocative and breath-taking lecture discussing the future of the pharmaceutical industry and the dramatic changes (both from a financial and technology point of view) that needs to be introduced to maintain profitability. Finally, at an integration session, reports from the breakout sessions were presented including the Conference conclusions and recommendations. In closing the Conference, the future role of EUFEPS was highlighted by Professor Ole Bjerrum presenting the EUFEPS initiative on "New Safe Medicines Faster" within the European Union.

Role of POC

In Session I, speakers reported on the role of proof of concept (POC) in the drug development process. Conceptual (Bühler) as well as industrial (Rapeport) and financial (Beaver) issues were covered. The Conference Chair, Professor Bühler defined POC as the pivotal decision point (Phase I/IIa) in the development of medicines, which shifts from process-based front loading to science-driven front loading and novel information management and decision making. The need to increase the signal: noise ratio in processes will be facilitated through new technologies (genomics, imaging). A framework for decision-making must include both the value and the cost of information-gathering activities. Formal approaches (cost-value modelling) can maximise the value of POC.

Impact of genomics

The second session addressed the impacts of genomics on POC. The impact of the HUGO project is believed to be dramatic, but the question of "when will genomics deliver?" was discussed. The understanding of the genetic factors involved in diseases will create new therapeutic targets as was exemplified for Alzheimer's disease. Transgenic animals will serve as pivotal instruments to this understanding (Herrling). With the anticipated availability of complete genomic sequences for an increasing number of organisms, opportunities abound for taking advantage of these data in identifying and prioritising new targets for drug development. Technology for combined use of genomic and genetic screens (Burks), as well as pharmacogenetic driven patient selection (Meyers), will improve the specificity and sensitivity of the POC process. A major conclusion derived from this session was that the concept of "one fits all" will not prevail and the discovery of "blockbusters" will be less common.

ADME and safety properties

As part of the optimisation of drug development, the application of POC principles for selection of candidate drugs was discussed. Presentations included the use of chemical property optimisation for proof of bioavailability (Lipinski), rapid *in vivo* PK screening (Cayen) and toxicogenomics and integrated toxicology screens (van Cauteren). It has become apparent that inappropriate pharmacokinetics (PK) is often the cause of failure in later clinical phases and the use of optimisation strategies such as chemical properties (rule of 5) and rapid PK screens can substantially improve the selection of (clinically)

viable candidates. Advances in analytical technology and modelling & simulation improves our ability to make valid predictions to man. With the arrival of toxicogenomics, the concept of toxicology screening will undergo a revolution since by the evaluation of altered gene expression patterns, the dose and time dependent mechanisms of toxic action can be identified before going into human trials. The identified biomarkers can then be applied to a mechanism-based safety evaluation in humans.

Preclinical POC value to man

Although the main theme of the Conference dealt with clinical POC, this session focused on the preclinical area and tried to answer the question of preclinical data and their predictive value to man. The key issue at hand is the relative lack of predictive, validated disease models in laboratory animals. During the session, pitfalls on the way to clinical POC (van der Graaf) as well as strategic improvements in models (Guentert) were highlighted. The complexity of receptor response in *in vitro* and *in vivo* systems can give misleading information due to the recent discovery of receptor "promiscuity" (agonist trafficking).

New biovalidation technology using mouse transformed into an in-vivo system carrying functional human tissues to enhance predictive models (exemplified for hepatitis) was also presented (Becker).

Early clinical development

The opportunities to facilitate POC in the very early clinical development stage were discussed in this session. Presentations included general (safety) requirements (Tomaszewski), first administration to man - FIM (Cohen), and the importance of metabolic profiling and prediction of interindividual variation (Meyer). A major conclusion derived from this session was that POC is of significant value and should be used to establish pharmacodynamic (PD) response. It is vital to develop PD (bio)markers early (start before FIM). Empirical approaches for dose selection in FIM studies (Maximum Tolerated Dose) was seriously questioned. The present "tolerability" concept should be redefined by using relevant biomarkers/symptom scores that express "toxic/undesired" events. A mechanistic PK/PD driven approach (including modelling & simulation) is of fundamental importance. It was suggested that MTD should be replaced by MDSS (maximum dose for satisfactory safety). Linear planning models should be abolished.

Biomarkers/surrogate endpoints

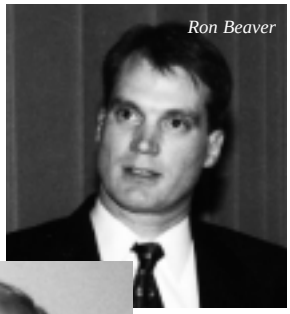
The value of biomarkers/surrogate endpoints to the POC process was highlighted in this session. Since hard clinical endpoints are difficult (to say impossible) to assess in the POC phase, biomarkers/surrogate endpoints play a pivotal role for POC studies. The controversy surrounding biomarkers (valid endpoints?) were extensively discussed from both an industrial and regulatory viewpoint (Atkinson). Despite some historical disappointments (antiarrythmics), the value of biomarkers was emphasised. They have been shown to have important utility that ranges far beyond the role of supporting drug approval, such as indicators of possible adverse events. Examples of valid biomarkers were given for novel biological targets, i.e. monoclonal antibodies (Stelzer), as well as for psychiatric disease (Deakin). Validation of proposed biomarkers in a drug development programme is fundamental.

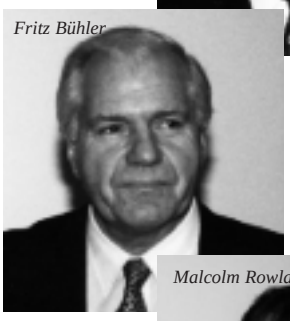
Design and analysis of POC trials

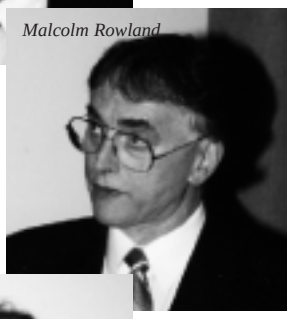
Designing and analysing POC trials was the topic of this important session. Presentations included requirements and general principles (Peck), the role of computer simulations (Hale) and novel designs (Grieve). It was emphasised that POC trials must be scientifically sound (randomised, blind, controlled, statistically powered, pre-specified, post-hoc analyses) and rigorously planned. If not, they can be misleading, costly, inefficient and leading to failed programmes. The "Peck Principles" - scientific integrity, aptness of endpoints, informative design and adequate analysis - were emphasised. It was proposed that simulation is consonant with the quality principles and is useful for planning of POC trials achieving optimal project value for termination or successful further development. The traditional designs and statistical analysis techniques presently used in typical POC trials are often (relatively) uninformative and should be improved. Adaptive designs, sequential decision models and Bayesian statistics, including non-linear mixed-effects modelling, was proposed to improve analysis of POC trials.

Regulatory issues

The last session was devoted to regulatory issues on POC and lean pivotal trials. Unfortunately, European regulators were not able to attend this session due to conflicting activities. FDA perspectives on the use of biomarkers were presented and the overall conclusion was that biomarkers are useful and important for the drug development process, provided expectations, relationships (validation) and purpose of inference are defined.


Ron Beaver


Fritz Bühler


Malcolm Rowland


Garth Rapeport

Photos: Basilisk

Participants

A total of 180 delegates from industry and academia in 13 countries participated in the Conference. The Conference attracted key people involved in drug development, especially from industry. All sessions were well attended and the discussions were intense and stimulating. It was truly a "working conference" with participants active even throughout the two evenings.

Future plans

The responses from the participants were very positive, and it was suggested that EUFEPS should continue this series of Conferences. A continuation is planned where focus will be on different pivotal strategies for the optimisation of drug development.


Photo: Nyhetstjänst

Anders Grahnén,
Assoc. Prof.
Conference Co-Chair

Symposium Report

3rd Central European Symposium on Pharmaceutical Technology

For the third time the Slovenian Pharmaceutical Society and the Faculty of Pharmacy, University of Ljubljana, Slovenia, organised the Central European Symposium on Pharmaceutical Technology under the patronage of the European Federation of Pharmaceutical Sciences (EUFEPS) and of the Slovenian Local Chapter of the Controlled Release Society (CRS), on September 23–24, 1999. The purpose of the Symposium was to present internationally recognised achievements of research laboratories of the pharmaceutical industries and universities in the areas of pharmaceutical technology, biopharmacy and pharmacokinetics. The Symposium ran on the regional level, and it ranked among 1999 European scientific meetings on the advancement of pharmaceutical sciences.

Outcome

The organisers decided to keep the Symposium open for all topics that belong to the area of pharmaceutical technology. Consequently, three main fields were offered again to the participants: new pharmaceutical dosage forms, new approaches in the manufacture of drugs, and recent achievements related to transport and interaction of active substances.

The Symposium was divided into four consecutive sessions, led by plenary presentations. Prof. Peppas, opening the first session, emphasised recent advances and molecular observations on the controlled drug and protein delivery. He illustrated this view by the results from his laboratory on the utilisation of mucoadhesive hydrogels, on site specific drug and protein delivery systems based on pH dependent hydrogels, and on glucose sensitive hydrogels for protein delivery. Prof. Florence underlined the importance of interaction of delivery systems with the biological environment as a nonpassive vector. He presented, on the basis of his experience, the interactions of nanoparticles with the intestinal epithelium, interactions of surfactant systems with biological membranes, and interactions of responsive hydrogels to external stimuli. Prof. Junginger presented a lecture on iontophoretic drug delivery, and he used apomorphine as an example on how to develop this kind of device from *in vitro* modelling to the patient.

Several speakers in the first session, as well as many presenters in the afternoon poster session, made the point that special attention should be paid to the properties of excipients (polymers, lipids, surfactants) such as rheological properties, charge, viscosity of dispersions, hydration, swelling and adhesion. They have a deciding influence on the processes taking place within the biological systems.

Among drug formulations special attention was drawn to the microcapsules, microspheres, niosomes, liposomes and hydrogels. A number of contributions dealt again with recent advances in the area of physical and chemical procedures used for enhancement or retardation of drug release from conventional dosage forms (powders, tablets, capsules, granules, pellets, suppositories, ointments, emulsions). Contributions covering special modes of application, such as transdermal, pulmonal, buccal and intravesical, were included in the programme, as well.

Prof. Conte started the third session of the Symposium. He delivered a presentation on the Geomatrix technology, a successful approach to develop a versatile drug delivery system using multi-layer tablet production. Prof. Schmidt presented pulmonary drug delivery from a tablet as a new device. In this session, many new approaches in the manufacture of dosage forms were given as free presentations.

Prof. Primožič opened the fourth session. He gave a lecture on recent advances in pharmacometric and regulatory aspects of bioequivalence. The role of models of growing complexity in the order *in vitro* models – cell cultures – isolated tissues – isolated organs – *in vivo* models, when studying transport and interactions of active substances before and after formulation, was presented in the contributions that followed. Understanding of these phenomena is of essential importance for the development of advanced controlled and targeting drug delivery systems.

Numbers

The Symposium attracted 150 participants from 13 European countries and the USA who participated actively as authors of oral communications (18) and poster presentations (58). The greatest attention was devoted to the plenary lectures (6). Extended two-pages abstracts were published in a special issue of Pharmaceutical Journal of Slovenia (Farm Vestn) which is available at the Slovenian Pharmaceutical Society. Two Vectorpharma awards were given to the authors of the best paper presented orally (M. Burjak et al: Development of mucoadhesive microspheres for intravesical application) and for the best poster (M. Wirth et al.: Wheat germ agglutinin-mediated drug delivery: gastrointestinal fate and transport studies using Caco-2 monolayers).

Relevance

The importance of the Symposium can be viewed as many-sided because it covered a broad range of areas of interest. First, scientific - the introduction of the ideas arisen from the presentations and discussions is expected to give an impetus to the generation of new knowledge. Second, ethical - because of direct applicability, the presented results will enhance the development of new drugs of better quality and with improved efficacy and safety profiles. Finally, social – the participants were enjoying beautiful settings of Portoroz together during informal meetings, and thus new collegial and friendly relations have been reestablished. Moreover, in conjunction with the Symposium, the 1999 EUFEPS Council meeting was held in Portoroz. The Council Dinner, organised in Strunjan, a small fishing village, offered tasteful seafood, which was flavoured with occasional speeches.

Perspectives

It was agreed during and after the Symposium that this scientific event will be strongly supported by EUFEPS, as well as by the central European national associations, also in the future. Also, the Central European Symposium on Pharmaceutical Technology should start to circle within the region, and it is foreseen that the fourth Symposium will be held in Vienna, Austria.

Aleš Mrhar, Professor
Symposium Chair

EU Update

Promoting Research activities within the European Community

By early 1999 the Fifth EU Framework Programme for Research and Technological Development (FP5) was launched by the European Commission. The Framework Programme is covering all areas of research and in the present programme, running from 1998 to 2002, the strategic objectives of the research programmes have been strengthened. This means that research results should lead to innovations, supporting the establishment of new companies and creating employment opportunities in Europe. Research project groups are therefore encouraged to have research partners both from academia and from industry.

Programme structure

FP5, based on four thematic and three horizontal programmes, contains two subprogrammes of most interest for us active in the pharmaceutical/medical sciences; the thematic programme "Quality of Life and Management of Living Resources" and the horizontal programme "Improving Human Research Potential & the Socio-economic Knowledge base". In the latter programme, a number of grants for training and mobility of researchers is available. For further information about this programme; please consult the web address:
www.cordis.lu/improving/home.html

Quality of Life Programme (QOL)

The QOL Programme consists of six research areas – Key Actions, such as food, nutrition & health, control of infectious diseases, the cell factory and the ageing population and disabilities. In addition, RTD activities of generic nature, support for infrastructures, fellowships and accompanying measures are available.

In March last year, the first call for applications was released with deadline in June 1999. The results of this call has now been communicated. As many as 1792 proposals were received, and the average project has 7.9 partners and a budgetary request of 1.8 million Euro each, all of them built on networks with participants from different groups/centres/industries in Europe. The industrial participation was quite high. About 50 % of the projects included at least one company.

During the last summer, the eligible proposals were evaluated by 992 independent experts from across Europe, working in panels under the supervision of scientific officers from the European Commission. In December 1999, the Commission approved the final set of proposals and in total 307 research projects were funded with an EU contribution of 494 million Euro. Thus the success rate for funding was about 18 %.

In the beginning of this year, most of the projects approved for funding have been started.

Further progress

The second call for application in the QOL Programme was announced in December 1999, with a deadline March 15, 2000. The application and evaluation process is restarted. For those of you interested in further details about the Programme, please consult the website: www.cordis.lu/life/home.html Additional deadlines are to follow.

Next steps

Already now, it is time to prepare for the next Research Framework Programme, FP6. During late spring this year the European Commission will launch an "Inventing tomorrow" document, pointing out the direction of the new FP and indicating what research areas to expose in the FP6. For this document, the Commission is collecting proposals and ideas from all parts of Europe. All Framework Programmes should, in the end, be approved by the Council (Member States) in a co-decision procedure with the European Parliament. This bottom-up process is necessary to achieve full commitment from all partners involved.

New Safe Medicines Faster

As you already know, the QOL Programme in FP5 does not contain a specific programme addressing the pharmaceutical/medical sciences. Therefore the Committee for Industrial Relations (CIR) of EUFEPS initiated the New Safe Medicines Faster Project, with the purpose that this proposal should be included as a Key Action in the FP6.

A first version of a Position Paper was submitted to the European Commission, approximately six months ago, and by applying for an Accompanying Measure support, a Workshop on the issue is arranged and partly funded by the Commission. Directors and scientific officers of the Commission have shown a great interest in this initiative, so the pharmaceutical/medical science is well on the track.

As stated above, all partners involved have to agree in the final end when setting the Programme. Therefore, we very much encourage all of you to be active in your home countries, by lobbying, especially the national bodies participating in the Programme discussions/settings and the negotiators at the EU level, for support of the proposal.

For further information on this important initiative – New Safe Medicines Faster – please contact the EUFEPS Secretariat (for address, see the front page of this Newsletter).

Maj-Inger Nilsson, Assoc. Prof.
Pharmacia & Upjohn, Brussels
EUFEPS Liaison Officer to EU

IPORSIP 2000
September 6-8 • 2000 • Istanbul • Turkey

This 2nd International Postgraduate Research Symposium on Pharmaceutics will provide a forum for the exchange of scientific information in the area of pharmaceutics. It is held under the auspices of AAPS, EPSA, EUFEPS, FIP and the Turkish Pharmaceutical Manufacturers' Association.

Graduate and undergraduate students, as well as postgraduate fellows, are invited to submit abstracts on their recent work in pharmaceutics (deadline: June 15, 2000), i.e. in:

Pharmaceutical Drug Delivery (PDD)
Physical Pharmacy (PP)
Radiopharmacy (RPh)
Pharmaceutical Technology (PT)
Pharmaceutical Biotechnology (PBIO)
Biopharmaceutics, Pharmacokinetics, Pharmacodynamics (BP/PK/PD)
Cosmetics (Cos)
Computer Aided Drug Design (CADD)
Clinical Pharmacy (CP)
Industrial Pharmacy (IP)
Community Pharmacy (COP)
Pharmacy Administration and Regulations (PA)

For more information on the programme, on registration fee, registration deadline, social program and instructions for abstract submission etc., contact the IPORSIP 2000 Secretariat, Istanbul Universitesi, Eczacilik Fakültesi, Farmasötik Teknoloji Anabilim Dali, TR-34452 Beyazit-Istanbul, Turkey. Tel +90 212 5282384 or +90 2125190904. Fax +90 212 5134222. E-mail: iporsip@turk.net

Posttidning B EUFEPS Newsletter, P.O. Box 1136, SE–111 81 Stockholm

Meeting Report

Lipid and Surfactant Dispersed Systems

After Istanbul, in 1997, and Beijing, in 1998, a scientific symposium were organised on September 26-28, 1999, in Moscow, Russia. Organisers were: APGI in collaboration with the Royal Pharmaceutical Society of Great Britain and the Lomonosov University of Moscow.

Theme and venue

The Symposium, the theme of which was: "Lipid and Surfactant Dispersed Systems", attracted both fundamentalists and specialists of a very wide range of applications of this type of product. Although a few explosions in Moscow buildings were cause for worry for a few of the participants, the Symposium took place in perfect calm at the President Hotel in the centre of Moscow.

Scientific content

As to the scientific content the Symposium was a true success. There were nine invited presentations by: D. Platikanov (Sofia), M. Ollivon (Paris-Sud), N.L. Klyachko and A.V. Levashov (Moscow), M.J. Lawrence (London), C.M. O'Driscoll (Dublin), E.D. Shchukin, E.A. Amelina and A.M. Parfenova (Moscow), V.N. Izmailova and G.P. Yampolskaya (Moscow), J.-L. Grossiord and M. Seiller (Paris-Sud), and V.P. Torchilin (Boston).

In addition, there were 20 oral presentations and 92 posters addressing the following topics: Fudamentals on surfactants, mono- and bilayers, micelles vesicles and liposomes; Formulation of micellar solutions, liposomes, simple mulsions, multiple emulsions; Evaluation of surface and interfacial properties, rheological behaviour, *in vitro* release and *in vivo* absorption; Pharmacological activity and applications.

Many delegates

The Symposium was just as successful in attracting a high number of participants, i.e. approx. 150 people representing 17 countries. It should be noted that, much to our satisfaction, there was a particularly high number of Russian participants, as the aim of this type of Symposium held abroad is to create contacts and collaboration with the host country.

Excellent collaboration

We must emphasise the excellent collaboration we had with the University, particularly with Professor Natalia I. Larionova, and the students of the Faculty of Chemistry at Lomonosov University in Moscow, who contributed to the local organisation of this Symposium. Without such help it would not have gone so smoothly and so joyously, as the gala evening demonstrated so well!

This type of happy, scientific experience will be renewed in other countries.

Prof. Dominique Duchêne
Université Paris-Sud, France

C A L E N D A R

SFSTP XXXII International Seminar: Control of Cleanliness – from manufacturing process to environmental issues
May 11-13, 2000, Montpellier, France
Contact: Société Française des Sciences et Techniques Pharmaceutiques, 5 Rue Basse des Carmes, FR-75005 Paris, France
Fax +33 1 43298252, Email info@sfstp.org

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CeR Lib Summer School: Free Radicals in Human Diseases
June 4-9, 2000, Aussoi, France
Contact: Arlette Alcaraz, CHU Grenoble Laboratoire de Biochimie, Box 217, FR-38043 Grenoble, France, Fax +33 4 76 765664
Email aalcaraz@chu-grenoble.fr

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DMW/ISSX 2000
June 11-16, 2000, Fife, Scotland, UK
Contact: Meeting Makers, Jordanhill Campus 76 Southbrae Drive, Glasgow G13 1PP, Scotland UK, Fax +44 141 434 1519

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24th International Symposium and Exhibition on High Performance Liquid Phase Separations and Related Techniques
June 24-30, 2000, Seattle, WA USA
Contact: www.stlcdg.org/hplc2000

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Controlled Release Society Workshops
July 7-8, 2000, Paris, France
In vitro/in vivo correlations applicable to extended-release formulations
Lipsomal therapeutics: gene therapy and more
What's new in cyclodextrin drug delivery?
Contact: Controlled Release Society, 1020 Milwaukee Avenue, Suite 335, Deerfield, IL 60015, USA, Fax +1 847 8087073
Email info@controlledrelease.org

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27th International Symposium on Controlled Release of Bioactive Materials
July 7-13, 2000, Paris, France
Contact: Controlled Release Society, 1020 Milwaukee Avenue, Suite 335, Deerfield, IL 60015, USA, Fax +1 847 8087073
Email info@controlledrelease.org

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13th International Symposium on Microsomes and Drug Oxidations
July 10-14, 2000, Stresa, Italy
Contact: Francesco de Matteis, Pharmacology Dept., University of Turin, Via P. Giuria 13, IT-10125 Turin, Italy, ax +39 011 6707788
Email fdem@medfarm.unito.it

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CPT 2000
4th Congress of the European Association for Clinical Pharmacology and Therapeutics
July 15-20, 2000, Florence, Italy
Contact: Newtours S.p.A., c/o Andrea Redditi Via S. Donato 20, IT-50127 Firenze, Italy
Fax +39 055 3361250
Email CPT2000@mail.newtours-CMO.it

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6th International Symposium on Biological Reactive Intermediates
July 16-20, 2000, Paris, France
Contact: Michéle Centonze Conseil, 6 bis, Rue des Cendriers, FR-75020 Paris, France
Fax +33 1 43496858
Email m-centonze-conseil.com

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10th International Pharmaceutical Technology Symposium (IPTS)
September 11-13, 2000, Istanbul, Turkey
Contact: Prof Dr Y. Capan or Prof Dr S. Kap.
Fax+90 312 3100906
Email huetb-e@tr-net.net.tr

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24th International Symposium and Exhibition on High Performance Liquid Phase Separations and Related Techniques
June 24-30, 2000, Seattle, WA USA
Contact: www.stlcdg.org/hplc2000

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Intermediate Level Workshop on PK/PD Data Analysis: A 4day Hands-on Course Using WinNonlin
Sept. 25-28, 2000, Château de Maffliers, France
Contact: APGI, Faculté de Pharmacie, Université Paris-Sud, Rue Jean Baptiste Clement, FR-92290 Chatenay Malabry, France, Fax +33 1 46835308, Email: apgi.apgi@cep.u-psud.fr
www.swepharm.se

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6th European Congress of Pharmaceutical Sciences & Short-Courses
September 16-19, 2000, Budapest, Hungary
Contact: EUFEPS 2000 Secretariat
P.O. Box 11, HU-2011 Budakalász, Hungary
Fax +36 26 343195 or 34042,
Email eufeps2000@mail.matav.hu
www.pharmweb.net/conference/eufeps2000.html

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7th EUFEPS Conference on Optimising Drug Development
November 13-15, 2000, Basle, Switzerland
Contact: EUFEPS Secretariat. B.O. Box 1136 SE-111 81 Stockholm, Sweden, Fax +46 8 4113217, Email secretariat@eufeps.org