EUFEPS

NEWS Letter

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Key EUFEPS Priorities

PRESIDENT'S REPORT

Professor Ole Bjerrum writes:
EUFEPS mission is to serve and advance excellence in both pharmaceutical sciences and innovative drug research in Europe. As incoming President, I will work sincerely for these aims, always conscious of the interests of scientists engaged in drug research and development, drug regulation, drug utilisation and drug policy making.

Complex process

The complete process for development of new medicines involves all the pharmaceutical sciences. Indeed, it is a very complex process with many scientific disciplines involved. Accordingly, it has numerous players within each country, as well as at the European level, in a number of learned societies. Looking at the situation objectively, Europe looks very fragmented. Without doubt, coordination and collaboration are essential ingredients to increase the competitiveness of Europe in the development of new medicines.

In my analysis, it is the drug development process that links the researchers together, irrespective of whether they come from academia, industry, clinical settings or regulatory agencies. In this regard, we are all in the same boat with the pharmaceutical industry as the engine. The well-being of all stakeholders in the pharmaceutical sciences depends on the overall competitiveness of the European pharmaceutical industry. The current situation is not very encouraging. This calls for action.

Who has the holistic view?

EUFEPS is the only one of the European learned societies that is trying to apply a holistic approach to the drug development process and, at the same time, houses scientists of nearly all the disciplines involved. They should be united through the research base of the pharmaceutical sciences.

This imposes a special responsibility on EUFEPS within the European scene. As President, I am ready to share in this responsibility; to advance pharmaceutical sciences in Europe for the benefit of the involved stakeholders. It should be possible to create a 'win-win' situation for the major actors involved: academia, industry, regulatory, patients and the public, if we can achieve more coordination and collaboration.

Who generates funding?

A precondition for establishment of a collaborative spirit between the partners is the availability of necessary resources and funding. From the EU perspective, only one major funding organ exists: The European Commission.

Therefore, EUFEPS has worked hard over the last four years to establish an understanding in Brussels for the needs of excellence among the pharmaceutical sciences in the drug development process. Our effort has been formulated through the initiative: New Safe Medicines Faster. It has been a success as

pharmaceutically relevant research, for the first time, has achieved a prominent position in the 6th Framework Programme (FP6) 2002-2006, which is linked to substantial funding. So far, only the first two calls of FP6 have been announced. Recently, it has been reported that additional pharmaceutically relevant topics are in the pipeline.

What can be achieved?

Under the heading of New Safe Medicines Faster, it is possible not only to apply under the announced calls such as "Integration Projects", "Networks of Excellence" and "Specific Support Actions", but also under pharmaceutically relevant new initiatives within the organisation of the European Research Area, such workshops, meetings, fellowships, training courses and other education (PhDs).

Technological platform for coordination

Today, coordination among the players in drug development to reach excellence in Europe is the most urgent challenge for the European pharmaceutical sciences.

Accordingly, EUFEPS has applied for EU money to create a new technological platform for drug development in Europe. It should be a supporting platform, primarily, which can assist, bring together and organise the stakeholders so that, from a European competitive point of view, the right activities within the pharmaceutical sciences can be initiated in Europe. This goes for academic, regulatory and industrial aspects. The needs of Small and Medium Enterprises (SMEs) receive special attention.

PharmSciFair

Another initiative, also based on the approach to create joint platforms, is the Pharmaceutical Sciences Fair & Exhibition – in short PharmSciFair. The first one will take place on June 12-17, 2005, in Nice, France. Here, EUFEPS provides the time frame and the space, and the participating organisations, the PharmSciFair Partners, contribute to the programme, by filling one or several sessions. The risk and revenue is based on shares.

Role of the "third force" for rethinking of drug development and approval

The present process of drug development and approval needs rethinking. No one has so far dared to address the process *ab initio* by building it up from scratch, taking into consideration all the new and emerging methodologies and techniques, which science now has to offer. The existing official organisations, e.g. EFPIA and EMEA, may not be able to attempt this rethinking, since industrial companies work towards fast development and approval of their own drug candidates and not towards general pre-competitive methodology. Furthermore, the companies seem to guard their own data. European regulators do not have their own research capabilities to contribute to renewal of the process. Evidence of new, reliable and useful techniques will have to be brought in from elsewhere. In this respect, academia has neither the resources nor the funds to conduct validation studies of these new techniques before they can be implemented.

To cope with this problem, we need consensus on what to do. Necessary research and validation will have to be established to provide the basis for a rational approach, which must include the regulatory point of view. It is my belief that the "third force", i.e. scientists as individuals – not as representatives of an organisation with their set of obligations and demands – could help tremendously to perform the analysis, in their personal capacities. Why not stimulate a concerted action by establishing a working group – a 'think-tank'? This group should propose radical changes, which are needed to exploit both available and emerging new methodology and technology. The adopted changes should be set in action in, say 10 years from now.

EUFEPS' day-to-day business

Parallel to the above-mentioned activities, EUFEPS continues with its efforts to arrange new and to develop well-established series of congresses and conferences, i.e. quality meeting places for pharmaceutical scientists. The recent Conference on "New Challenges in Drug Delivery", held in September 2003, in Versailles, together with APGI demonstrated that EUFEPS is also open to organising events together with its Member Societies. Within niches, where needs to advance the pharmaceutical sciences in Europe have been identified, EUFEPS will continue to take action e.g. by initiating meetings, workshops and training courses.

In closing

To strengthen the European competitiveness in drug development, the essential instruments are the creation of European scientific and technological platforms, the activation of the "third force" and more funding for pre-competitive research activities. EUFEPS will not only encourage such initiatives, it will engage in them. Beyond this, EUFEPS will continue to attend to its other activities in important fields in the times to come.

Ole J Bjerrum, Professor
EUFEPS President

EJPS adds Regulatory Intelligence

As an enhancement to the European Journal of Pharmaceutical Sciences, Carolyn Hynes will be contributing articles about the latest information and intelligence on drug regulatory matters across Europe.

Carolyn Hynes, PhD, is a Manager in the European Regulatory Affairs Department of Johnson & Johnson Pharmaceutical R&D in the UK. Carolyn works within the group responsible for regulatory intelligence and external affairs. Her main responsibilities include locating and disseminating both information and intelligence on the European regulatory environment within the company. Prior to joining J&J in 2001, she worked as a Regulatory Projects Manager at CMR International, an independent research organisation, which identifies key trends and strategic drivers within pharmaceutical R&D.

Carolyn has submitted a first article on the Clinical Trials Directive and the impact its implementation will have on the regulation of clinical research in Europe. Possible topics for the future include;

- Preparations for EU enlargement-Regulatory issues
- Review of EU pharmaceutical legislation
- Proposals for paediatric legislation in the EU
- Orphan drug legislation
- EMEA-FDA interactions

More reasons to read EJPS

Carolyn Hynes

Quality Management in Pharma and Biotech

Rogério Gaspar, Professor at the University of Coimbra, Portugal, gave an excellent presentation on regulatory issues in drug delivery at the EUFEPS Conference, in September 2003, in Versailles, France. His final recommendation was "to reduce the regulatory burden by establishing an appropriate Quality Assurance System from the start and throughout all Development Stages".

Indeed, employees of pharmaceutical companies, who are active in research, product development, production or quality control are dealing with the complexity of quality assurance systems on a daily basis. For them, it is important to have an overview of these systems in order to improve quality management in their own environment.

EUFEPS has presented its Vision on Training and Education in this field in the EUFEPS Newsletter, September 2003, which reflects Prof. Gaspar's opinion on the need for implementation of quality awareness and quality systems from the very early stages onwards.

In this regard we are glad that we can offer now a Training Course on Quality Management in Pharma and Biotech.

The course intends to convey the notion that quality can and must be designed into all aspects of the research, development, and manufacturing operations in contemporary pharmaceutical and biopharmaceutical companies.

Therefore, the faculty of this course is to a large extent selected from both industry and public health authorities; the rationale being that a better understanding of each other's positions will lead to a more proactive attitude from the industry regarding quality issues.

In current academic curricula, quality is now beginning to be recognised as an essential aspect of any industrial activity, and in particular in the (bio)pharmaceutical industry. However, it is not yet a fully integrated part of these curricula; the reason for the creation of this course.

The course is intended for:

- Professionals in the pharmaceutical and biotechnology industries
- Professionals in institutions and contract research organisations
- Hospital pharmacists
- Postgraduate students planning an industrial career

The course consists of the following modules, each with a duration of 3-4 days:

Module 1 (2-4 February 2004): Good Quality Management, the role of the Qualified Person

Module 2 (29 March – 1 April 2004): From idea to registration dossier: Good Practices in research, development and production of pharmaceutical products

Module 3 (7-9 June 2004): Sterile manufacturing

Module 4 (27-29 October 2004): Quality and safety of biopharmaceuticals: from genetics to downstream processing

The modules will be offered at different locations in The Netherlands and Belgium, and will sometimes include an optional excursion to a pharmaceutical company.

We from EUFEPS feel that this course programme offers a comprehensive overview and it helps to shape the future. It is a unique opportunity to fill urgent needs in a structured way.

Hans H. Lindén, M.Sc.
Executive Director, EUFEPS

Bernd Clement, Professor
Chair EUFEPS Committee on Training and Education (CTE)

Pharmaceutical Topic in the third call for FP6 proposals

From EU Directorate Research, EUFEPS has learnt that the Commission intends to call for proposals in an integrative project, which closely follows the EUFEPS initiative New Safe Medicines Faster. Please note that this information has not yet been officially approved.

The elements of the announcement with the title "New Approaches for Accelerated Development of New Safe Medicines" cover:

1. Generation of a vision and global strategy to reach the goal of NSMF
2. Analysis of bottlenecks and barriers
3. Recommendation for their remedy, using recent and emerging scientific accomplishments
4. Identification of new approaches and methodologies to achieve NSMF
5. The use of a chronic disease to show the utility of such a road map
6. Concrete research projects and demonstration areas to fulfil the plans
7. Involvement of all relevant disciplines and stakeholders, including small and medium enterprises (SME's)

EUFEPS has pointed out to the Commission that it is not yet clear how much experimental research can be supported in this integrated project. In our opinion, if we first have to wait 3-4 years for a recommendation of what to do, it is not so interesting. On the other hand, if the work of "A think tank on NSMF" and experimental research go hand in hand, the call opens up very interesting perspectives.

Take this as an indication for the impact and strength of the New Safe Medicines Faster concept, and consider how you, your colleagues, collaborators and other stakeholders in the drug development process can exploit the call.

Ole J. Bjerrum

The Pharmacopoeial Column

Henk De Jong describes important recent progress on the concept of interchangeability

When Dr. C.A. Johnson of the British Pharmacopoeia spoke about international harmonization at the 1975 Congress of the Féderation Internationale Pharmaceutique (FIP), in Dublin, he nicely listed the key factors in the harmonization process as being: History, Environment, Law and Language. When taking the initial letters of these words, they spell the word that rather frequently comes to the minds of people trying to harmonise. Of course, these key factors play an important role and are the origin of the so called "sticky points". These are differences that cannot easily be resolved since they touch on many other issues e.g change of a reagent used in a large number of places or a general method not (yet) harmonised.

With a glimpse of paradise, participants in the ICH6 conference, held in Osaka Japan, from 12-15th November 2003, learned that, during the meetings of the regulators from the ICH regions, agreement was expressed on the interchangeability concept. This was (partly) based on the results of a collaborative study on calcium phosphate (an important tabletting ingredient) performed by members of Tri-PEC, the International Pharmaceutical Excipients Councils from USA, Japan and Europe. The study showed that while the assay methods in USP, Ph.Eur. and JP are different, the results are the same and the methods are equivalent. The recommendation of Tri-PEC to the Pharmacopoeial Discussion Group (PDG) was to retain the current methods in each Pharmacopoeia and add a statement that they are interchangeable.

This means that companies in the three regions will not need to change their registration dossiers, their laboratory procedures, their SOPs, their technician training schemes etc., if and when the regulators agree with this recommendation. Several worldwide operating companies already have data on quality of ingredients as tested according to the three Pharmacopoeias; these can serve to speed up the harmonisation process. In selected cases, direct comparative laboratory work may be necessary to address a specific issue.

At the same event, the ICH Steering Committee approved the activation of Quality item four: "Q4, Pharmacopoeial Interchangeability". An expert working group will be formed, consisting of the ICH parties, to develop the process. The activation of Q4 will bring the regulators into the Pharmacopeial harmonization process at the stage of PDG-sign off and will help to stimulate implementation of harmonized compendial texts.

Henk J. de Jong

New Safe Medicines Faster Award, 2003

This new EUFEPS Prize was first awarded at the 1st EUFEPS Conference on Optimising Drug Delivery and Formulation: New Challenges in Drug Delivery, on September 29, 2003, in Versailles. The award given to the three professors, Mats Bergström, Anders Grahnén and Bengt Långström of Uppsala University, for their contribution to the ***microdosing concept****.*

Left to right: Profs. Grahnén, Bergström, Långström and Bjerrum.

The microdosing concept includes dosing to man in the range of 1/100 – 1/1000th of the normal dosage. A compound is labelled with a radionuclide of high specificity allowing measurement of its distribution through sensitive techniques like Positron Emission Tomography (PET) or Accelerator Mass Spectrometry. The low dose sets modest regulatory requirements before actual testing. Microdosing represents a new paradigm, since human becomes a species for candidate selection. In this way "First in Man" is brought forward in time.

Thus, the invention is in full accordance with the founding text (see box):

Microdosing is a new innovation, which has been experimentally proven. It represents a precompetitive methodology that has been accepted by regulatory authorities. Through wider application, it has the potential both to shorten and to increase the capacity of the drug development process significantly. This means microdosing will contribute to a more efficient drug development.

Further reading about the microdosing concept can be found in Bergström M, Grahnén A, Långström B. Positron emission tomography: a new concept with application in tracer and early clinical drug development. Eur J Clin Pharmacol (2003) 59: 357-366

Ole J. Bjerrum

The founding text for the award runs as follows: "To honour an individual – or team – of scientists for outstanding contribution to the innovation and advancement of new methodology or technology which significantly has contributed to shorten or to make the drug development process more efficient".

The award, together with 3000 EURO, is sponsored by Aventis and the nomination is done solely at the discretion of the EUFEPS Committee on Awards and Prizes (CAP).

Highlights from the European Journal of Pharmaceutical Sciences

Doude van Troostwijk and coworkers from The Netherlands investigated pharmacokinetics of clozapine (Eur J Pharm Sci 20: 451-457, 2003). This drug is used as antipsychotic, but there are interindividual differences in the efficacy that cause dosage variation in the clinical practice. For that reason, the activity of CYP1A2 was correlated with the pharmacokinetics of clozapine in schizophrenic patients. In 22 patients, the CYP1A2 activity and the clozapine clearance were estimated. Pharmacokinetic parameters of clozapine were studied using population PK software and Bayesian analysis. Caffeine clearance was used as an indicator of CYP1A2 activity. In psychiatric patients, CYP1A2 activity seemed to be an important determinant of the variability of effective clozapine doses.

Methods for early prediction of drug absorption are important aid in drug discovery process. Data from such methods help to select right compounds for further development. Ruell, Tsinman and Avdeef (Eur J Pharm Sci 20: 393-402, 2003) investigated the PAMPA absorption model that is based on the use of lipoidal membranes for prediction of transcellular permeation of drug candidates. In such models the unstirred water layer on the membrane surface may cause bias in the results particularly in the case of highly lipophilic compounds that may have the unstirred water layer, instead of the actual membrane, as the rate limiting factor in permeation. The authors describe a method that is based on optimally selected pH value for the determination (pKaflux) . The method described here enabled estimation of true membrane permeability over a pH-range.

Miniaturisation is changing the field of analytical chemistry at a rapid pace. Recent exciting developments in this field were reviewed by Huikko, Kostiainen and Kotiaho (Eur J Pharm Sci 20: 149-171, 2003). These systems are described as labs on chips. Such devices include functional units for sample loading, reactions, separation and detection. Preparation methods, technological features, and applications are described in the review article.

Metabolic drug-drug interations may influence the efficacy and safety of drug treatment. These interactions are dependent, beyond events at the enzyme level, also on the dosing regimen and pharmacokinetic features. Yang et al. (Eur J Pharm Sci 20: 223-232, 2003) from Sheffield demonstrate the impact of dose staggering on metabolic drug-drug interactions. Kinetic models were developed and evaluated by comparing the simulations to the data in humans (e.g. budesonide and ketoconazole; triazolam and itraconazole). Such modeling approach is useful in the design of dose staggering during polypharmacy.

Arto Urtti, Professor
Editor EJPS

PDS Awards

The International Society for Pharmacoepidemiology has an annual award for the best paper published in the Society's journal, Pharmacoepidemiology and Drug Safety. This year's award was divided between two papers, both on the same topic: post-marketing changes in recommended doses. The two papers were:

Cross J, Lee H, Westelinck A, Nelson J, Grudzinskas C, Peck C.
Postmarketing drug dosage changes of 499 FDA-approved new molecular entities, 1980-1999. Pharmacoepidemiol Drug Safety 11: 439-46, 2002.

and

Heerdink ER, Urquhart J, Leufkens HG.
Changes in prescribed drug dose after market introduction. Pharmacoepidemiol Drug Safety 11: 447-453, 2002.

They were accompanied by an editorial:
Struijker-Boudier HAJ.
A drug is not a drug is not a drug: a commentary. Pharmacoepidemiol Drug Safety 11: 437-8, 2002.

Strong links to EUFEPS came through extensive discussion of the study results during the 10th Conference on Optimizing Drug Development: Getting the Dose Right, held in Basel, Switzerland during December 2002.

The two studies, which came to essentially the same conclusions, used different methods. The conclusions were: (a) 50% or greater reductions in recommended dose constituted the vast majority of the changes that occurred with drugs having indications outside the category of anti-infective agents; (b) most of the changes that occurred with anti-infective agents were dose increases; (c) the number of dose-reductions occurring amongst drugs outside the anti-infective field has been rising since 1990; (d) one non-anti-infective drug in ca. 4.5 has undergone at least a 50% reduction in recommended dose since 1980. Most pharmaceuticals are priced on a weight basis, so a reduction in recommended dose is usually associated with a fall in revenues from product sales. It is unclear the extent to which the rising number of post-marketing dose-reductions since 1990 is attributable to rising economic incentives for challenging the recommended regimens, created by steep increases in pharmaceutical prices, or a higher incidence of mistaken estimates of optimal dosing made during premarket development.

John Urquhart, Professor
Pharmacol-epidemiology Group, Department of Epidemiology, Maastricht University, NL
H.G.M. Leufkens,, Professor
Department of Pharmaco-epidemiology and Therapeutics School of Pharmacy, University of Utrecht, NL

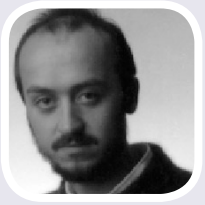
New EUFEPS Faces

Prior to and at Council in September 2003, new representatives to Council were elected, as were new members of the Executive Committee, all for two years (see Executive Report).

The Individual Membership representatives are:

Prof. Maria Alonso, Santiago de Compostela, ES

Prof. John Caldwell, Liverpool, UK



Prof. Stefaan de Smedt, Gent, BE

Dr Thomas Österberg, Stockholm, SE

New members of the Executive Committee include:

Prof. Theo Dingermann, Frankfurt, DE

Dr Chris Doherty, Macclesfield, UK

Welcome aboard!

EXECUTIVE REPORT

December 2003

Successful meetings

The 2003 Council and Open Forum were held on September 28, 2003, in historic Versailles, FR. There were Executive Committee meetings before and after Council. Actually, the series of meetings in Versailles started with the Committee on Training and Education (CTE) and ended, a few days later, with a meeting with the Committee on Industrial Relations (CIR). In between, there was the First EUFEPS Conference on Optimising Drug Delivery and Formulation: New Challenges in Drug Delivery, organised with APGI (Association de Pharmacie Galénique Industrielle).

Without doubt, the meetings and the conference were successful ones, reflecting kinship, new information and excellent science, as well as better, stronger relationships within the current family of pharmaceutical sciences associations in Europe. One new Member Society – the Romanian Pharmaceutical Society – expanded the family, at this Council. Now, EUFEPS comprises 25 Member Societies in 24 countries. One of these countries, Germany, is represented by the DPhG (German Pharmaceutical Society) and the APV (International Association for Pharmaceutical Technology). A growing number of paying Individual Members of EUFEPS (nearly 500) have decided to support and have direct links to the European setting, in addition to their local and/or national membership.

The Executive Committee met next, on November 22-23, 2003, in Amsterdam, NL, where substantial time was spent on critical issues of recognition, visibility and development of EUFEPS. In conjunction with this, the Executive had a meeting with the leadership of the ULLA consortium (Universities of Uppsala SE, London UK, Leiden NL, Amsterdam NL, Copenhagen DK and Paris-South FR) to discuss training needs in the pharmaceutical sciences. The first Executive Committee, in 2004, is scheduled for January 24-25, in Brussels, and it will be held partly with CIR. Additional ones, in 2004, are planned for April, June, October and December.

European voice

Obviously, there are a number of European countries and associations engaged in pharmaceutical sciences, which do not yet have voice and vote in EUFEPS. Some of these associations have not yet decided to join EUFEPS. Perhaps, since they are not aware of us, or do not see why they should join. Others would very much like to join, but they cannot afford it, currently. Whatever the reason, the stronger EUFEPS grows, the stronger becomes the European pharmaceutical sciences voice on the European and Global scenes.

In the World, there are 194 states, currently (Statesman's Yearbook 2003). Out of these, 43 are European, ranging from a population of 27 000 inhabitants (San Marino) to one of 145.5 million (Russia). Probably, no one knows how many scientific associations there are altogether in Europe, representing any aspect of science relevant for developing new safe medicines for their own and other citizens. EUFEPS will have to map the associations.

New information

After a dozen years of experience, the Council agenda is well defined. However, on the Agenda for this Council, there was a new item, namely; Reports from Member Societies and Individual Members. These reports added up to an impressive list of national, regional and international events in Europe. All societies, or sections of them, have their own well-attended meetings, courses and conferences, some many and others fewer, depending on their size and the resources available to them. Many societies collaborate with, usually neighbouring, country societies to establish regional meetings, courses and (summer) schools on important topics. Several societies are engaged in the organisation of international (and World) meetings in Europe, including those in collaboration with non-European organisations. A few societies publish their own journals. A couple of societies have a seat on the FIP Board of Pharmaceutical Sciences (BPS). Several Member Societies have decided to join, or are considering joining, the Pharmaceutical Sciences Fair initiative. As to the Individual Members, it was clearly stated that it's very important to identify and create ways to spread information about EUFEPS. Appointing "EUFEPS Ambassadors" was, for example, strongly recommended.

Some of the Member Societies indicated that they have, or are working on, a strategic plan for their future activities, but also on their future role, ambitions and support of the European scene and EUFEPS. The standard set of questions for such endeavours include: What, when and why? In this case, they will

have to be related to engagements on the National level, on the European level and on the Global level, in the mission-vision-strategy-action chain of considerations needed for a plan. And also, as always: How to finance it?

As to the number of meetings – and Journals, perhaps – better European coordination, co-operation and collaboration were requested. Again, it was stated that no one other than EUFEPS could do it. The EUFEPS-APGI organisation of the 2003 Versailles Conference, which is more than co-sponsorship with no financial obligations, and the forthcoming 2005 Pharmaceutical Sciences Fair in Nice, FR were said to be good models or platforms on which to build. EUFEPS should also facilitate access to information about Member Society events, in addition to the Newsletter Calendar, by posting a link on the front page of EUFEPS Online (www.eufeps.org shows that this has been done). Over the years, it has also been recommended that EUFEPS should be engaged in all but truly National meetings, i.e. as EUFEPS Member Societies go European and/or International.

Finance

The financial outcome for 2002 was reported and approved by Council, including a small positive result. Furthermore, it was expected that expenses for 2003 would be covered by income, although there was one important event left. Industry, particularly, register late nowadays and the number of delegates was not yet known for the December EUFEPS Optimising Drug Development Conference in Basel, CH.

The Council approved a well-balanced budget for 2004, proposed by the Executive Committee. In this, membership fees were unchanged, although the extra support by the Swedish Academy of Pharmaceutical Sciences (SAPS) will be further reduced, next year. The 2005 budget, at next Council, may be trickier. At this Council, SAPS reported that, from 2005 onwards, there would no longer be any extra SAPS funding available for EUFEPS. Other sources will have to be identified for any "extra" support needed.

Elections

At this Council, Prof. Theo Dingermann (Frankfurt, DE) and Dr Chris Doherty (Macclesfield, UK), one representing academia and one industry, were elected as new members of the Executive Committee, for two years. Members of the Executive Committee elected earlier include: Prof. Ole J. Bjerrum, President (Copenhagen, DK), Prof. Christian Noe, President-Elect (Vienna, AT), Prof. Dominique Duchêne, Immediate Past-President (Paris, FR), Prof. Conny Bogentoft, Treasurer (Stockholm, SE), Dr Altan Demirdere (Istanbul, TR), Prof. Aleš Mrhar (Ljubljana, SI), and Prof. Rodolfo Paoletti (Milan, IT). In addition, the Executive Director of EUFEPS is member of the Committee, *ex officio*, with voice but no vote.

Prior to Council, the Individual Membership had re-elected Prof. John Caldwell (Liverpool, UK) as Representative to Council for an additional two-year term, as well as three new ones, also for two years, Prof. María Alonso (Santiago de Compostela, ES), Prof. Stefaan de Smedt (Gent, BE), and Dr Thomas Österberg (Stockholm, SE). This means double the previous strength, due to the increase in Individual Membership.

Forthcoming events and challenges

Preparations are underway for several EUFEPS conferences and courses, as well as for the next Congress. See announcements on them, which are published and circulating, or consult designated EUFEPS Online pages for more information (www.eufeps.org).

There are events posted for 2005, including the 3rd World Conference on Drug Absorption, Transport and Delivery in April in Barcelona, ES, and the Pharmaceutical Sciences Fair in June in Nice, FR. For the latter, we are bringing it all together and formalising commitments to the scientific and other programmes, exhibitions, publicity, organisation, venue, finance, etc. Upfront payment is, for example, required to secure the reservation of the Acropolis Centre in Nice. In this project, the number of organising and collaborating partners and cultures is higher than for any pharmaceutical sciences event held anywhere to date. Reflecting Europe in a nutshell, it will require special attention and consideration – and, perhaps, some patience as well.

Hans H. Lindén
Executive Director, EUFEPS

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CALENDAR

Advanced Structural Chemistry and Molecular Modelling
February 16-27, 2004, Copenhagen, Denmark
Contact: Flemming Steen Jörgensen, Danish University of Pharmaceutical Sciences Universitetsparken 2, DK-2100 Copenhagen Denmark, Fax +45 35 306001

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International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology 2004
March 15-18, 2004, Nuremberg, Germany
Contact: APV (International Association for Pharmaceutical Technology), Kurfürstenstrasse 59 DE-55118 Mainz, Germany, Fax +49 6131 976969 Email 2004@apv-mainz.de
Website www.apv-mainz.de/English/frame.html

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EUFEPS 2004

Building on the success of EUFEPS 2002, the theme of EUFEPS 2004 is New Safe Medicines: Towards Mechanistic Prediction – Building European Science Networks and Opportunities.

Tentative Programme

Major streams and topics of EUFEPS 2004 include:

- *In vitro* and *In silico* approaches to prediction of DM/PK/PD profiles;
- Efficacy, drug-induced toxicity and safety prediction, utilising "omics" and biomarkers;
- New and predictive approaches for safe and effective delivery of small drug molecules, as well as genes, proteins and vaccines;
- Process analytical technology (PAT) for predictive and science based processing;
- Innovations in drug development – including microdosing, imaging, knock-in/knock-out systems, and more.

The three-day programme will comprise Keynote and Plenary Presentations; Parallel Symposium Sessions; Small Group Meetings; Poster Sessions; and an Integrated Exhibition.

Call for Abstracts

Abstracts can be from any area of the pharmaceutical sciences. **Submission deadline is May 15, 2004**. Posters and the Exhibition will be combined, close to the area for coffee and lunch breaks.

Exhibition

Providers of technical instruments, equipment and know-how, as well as of books, training and education, computer software and other items and service needed for the whole process of drug discovery, development, distribution and evaluation of medicines are invited to exhibit at the EUFEPS 2004.

More information

See circulating announcements or consult the EUFEPS Online (www.eufeps.org).

Drug Design and Discovery
March 15-19, 2004, Copenhagen, Denmark
Contact: Povl Krogsgaard-Larsen, Danish University of Pharmaceutical Sciences Universitetsparken 2, DK-2100 Copenhagen Denmark, Fax +45 35 306001

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DUPHAT 2004
March 20-22, 2004, Dubai, United Arab Emirates
Contact: INDEX Conferences & Exhibitions Organisation, P.O. Box 13636, Dubai, UAE
Fax +971 4 2651581, Email index@emirates.net.ae
Website www.indexexhibitions.com

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Advanced Methods in Pharmacokinetics and Pharmacodynamics: A one week workshop
March 28 – April 2, 2004, Sils Maria, Switzerland
Contact: Irene Sung, School of Pharmacy and Pharmaceutical Sciences, University of Manchester, Manchester M13 9PL, UK
Fax +44 161 2738196
Email irenesung-pkworkshops@man.ac.uk
Website www.pkworkshops.man.ac.uk

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EUFEPS Conference on Drug Transporters: Integrative approaches in ADME research
April 19-21, 2004, Copenhagen, Denmark
Contact: EUFEPS Secretariat
P.O. Box 1136, SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org
Website www.eufeps.org

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EUFEPS Training Course on HT Drug Metabolism/Disposition
April 22-29, 2004, Amsterdam The Netherlands
Contact: EUFEPS Secretariat
P.O. Box 1136, SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org
Website www.eufeps.org

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Receptor Structure and Function
April 26-30, 2004, Copenhagen Denmark
Contact: Jette Sandholm Kastrup, Danish University of Pharmaceutical Sciences Universitetsparken 2, DK-2100 Copenhagen Denmark, Fax +45 35 306001

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Optimizing Outcomes in Pharmacotherapy. 2nd ACCP-ESCP Joint Meeting
April 28-30, 2004, Paris, France
Contact: ACCP, 3101 Broadway, Suite 650 Kansas City, MO 64111, USA
Email accp@accp.com, Website www.accp.com
or ESCP International Office, Avenue des Gaulois, 7, BE-1040 Brussels, Belgium
Fax +32 2 7431550, Email escp@associationhq.com
Website www.escp.nl

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European Conference on Drug Delivery and Pharmaceutical Technology
May 10-12, 2004, Sevilla, Spain
Contact: APGI, 5, Rue Jean –Baptiste Clément FR-92296 Chatenay-Malabry Cedex, France
Fax +33 1 46835308
Website www.apgi.org/congress/sevilla.htm

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Pharmaceutical Sciences World Congress (PSWC2004)
May 29-June 3, 2004, Kyoto, Japan
Contact: PSWC Secretariat, c/o Business Center for Academic Societies Japan, 7F Flora Building 4-2-8 Hongo, Bunkyo-ku, Tokyo 113-0033 Japan
Tel +81 3 3815 1681, Fax +81 3 3815 1691
Email pswc2004@bcasj.or.jp

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Advancing Outcomes Research Methodology and Clinical Applications
June 20-29, 2004, Boston MA, USA
Contact: ISOQOL, 6728 Old McLean Village Drive, McLean, VA 22101 USA
Fax +1 703 5568729, Email info@isoqol.org
Website www.isoqol.org

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Workshop in Basic Pharmacokinetics
July 11-16, 2004, Arosa, Switzerland
Contact: Irene Sung, School of Pharmacy and Pharmaceutical Sciences, University of Manchester, Manchester M13 9PL, UK
Fax +44 161 2738196
Email irenesung-pkworkshops@man.ac.uk
Website www.pkworkshops.man.ac.uk

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Pharmacogenomics in Drug Research and Development – From Drug Discovery to Marketing, Possibilities and Pitfalls
August 15-20, 2004
Contact: Claus Möldrup, Danish University of Pharmaceutical Sciences, Universitetsparken 2 DK-2100 Copenhagen, Denmark
Fax +45 35 306001

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2nd Biologie Prospective Santorini Conference "From Human Genetic Variations to Prediction of Risks and Responses to the Environment"
September 30-October 4, 2004, Santorini, Greece
Contact: Biologie Prospective, Inserm U.525 Université Henri Poincaré, 30 Rue Lionnois FR-54000 Nancy, France, Fax +33 3 83321322
Email Gerard.siest@pharma.uhp-nancy.fr

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Quality on the move: Dynamics of the European Pharmacopoeia
October 4-6, 2004, Budapest, Hungary
Contact: Public Relation Unit, EDQM, European Pharmacopoeia, 226 Avenue de Colmar, BP 907 FR-67029 Strasbourg Cedex 1, France
Fax +33 3 88412771
Email publicrelations@pheur.org

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Optimising Biotech Medicines
October 14-15, 2004, Brussels, Belgium
Contact: EUFEPS Secretariat
P.O. Box 1136, SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org
Website www.eufeps.org

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EUFEPS 2004. New Safe Medicines: Towards Mechanistic Prediction
October 17-20, 2004, Brussels, Belgium
Contact: EUFEPS Secretariat
P.O. Box 1136, SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org
Website www.eufeps.org