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EUFEPS 2002: New Safe Medicines Faster

An Integrated Congress Report

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EUFEPS

EUROPEAN FEDERATION FOR PHARMACEUTICAL SCIENCES

EUFEPS 2002:

New Safe Medicines Faster

An Integrated Congress

Report

Report from the Congress held on October 20-23
Stockholm, Sweden

European Federation for Pharmaceutical Sciences – EUFEPS
Financially supported by the European Commission

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Preface

International scientific congresses seem to have reached an optimal organization structure. At least the structure has not changed very much over the last 30 years. Accordingly when EUFEPS planned their biannual congress on pharmaceutical sciences 2002, it followed the traditional scheme: plenary lectures, parallel sessions, posters, and exhibitions. However the scientific content was organized on a process basis rather than on a scientific discipline basis.

In the emerging biotech sector things were organized differently. Here the entrepreneurial aspects were much more to the fore: presentation of company profiles, venture capital, patenting, job offering, training, education etc. Such events could collectively be called para-scientific activities. EUFEPS realized that future successes in number of attendees lie in the offering of similar events in combination with its normal scientific programme on the pharmaceutical sciences. In principle the EUFEPS congress covered the same topics, as the pharma biotech congresses as development of medicines were the common objective.

For this reason an extra organizational committee was set up for the purpose to organize, in parallel to the ordinary scientific programme, such para-scientific events.

Realizing that this, for EUFEPS, first event would be risky business if conducted in scale needed to get impact an application was put together for the EU Commission under the accompanying programme. It was sent in October 2001 and final approval was obtained March 2002. The receipt of this generous grant from EU is gratefully acknowledged. Without the support we could not have organized para-scientific events in conjunction with our scientific congress programme.

The reporting to the EU Commission takes place through this report. It is built up in such a way that it also should be of use for organizers that want to integrate such para-scientific events in their future congresses.

The organizing committee wants on this occasion to thank all involved persons that made this event possible. The EUFEPS office (Hans Lindén and Annika Nyman) has been particularly helpful.

Copenhagen, 30th December 2002

Ole J Bjerrum (chair), Copenhagen DK
Fritz R Bühler, Basel CH
Giovanni Gaviraghi, Siena IT
Hans H Lindén, Stockholm SE
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Claes Post, Stockholm SE
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1 Executive summary

Our vision was to create a new standard for scientific congresses of the future, using as a model the EUFEPS 2002 New Safe Medicines Faster congress held in Stockholm October 20-23 2002, thereby supporting the creation of a European Research Area (ERA) for drug development sciences. This was achieved through the following three objectives.

- Organize a first class scientific programme around the theme.
- Gather around this core all the auxiliary disciplines and supporting organizations necessary to serve the needs of the participants regarding research industrial collaboration, ethics, training and education, job search and recruitment, entrepreneurship and start-ups finance and funding (including FP6 represented by the Commission) together with integration of press and patients' organizations.
- Assist the audience in a planned way to prepare and organize for networking and formation of integrated projects with regard to future applications for FP6.

For a congress of pharmaceutical sciences gathered around the initiative New Safe Medicines Faster, the process aspect was central. Promotion of pure, basic and applied science alone is not enough to create the desired deliverables in the form of medicines. What is needed is further integration of the process with an array of para-scientific aids. The many new sources of research funding have become increasingly important, now, where the route from the academic researcher to start-up company is so short.

Three new modes of events were introduced: Afternoon Specials, Forum Events and EU Networking and Consortia Building Meeting. Eleven Afternoon Specials were organized focusing on the innovation for new chemical entities, for science driven regulation, and for biotech on SME. "Ethical aspects and Dialogue with public" covered the pharma/public interface. "Training and education" had two sessions on the need for pan European training aspects. Finally the European dimension was covered by the session for "The 6th Framework Programme", "Scientific east-west integration" and the role of "The European scientific organizations working in the area of pharmaceutical sciences". More the 250 participants joined the Afternoon Specials with a remarkably even distribution of people between various sessions.

The Forum Events were not the success we had hoped for due to appearance of too few actors. The activities covered were EU Directorate for Research, regulators, finance, big pharma, ethicists, the press, SMEs, European science organizations. Formal and informal activities took place.

The EU Networking and Consortia Meeting laid the foundation for future applications to FP6 with EUFEPS as an active coordinator.

All beginnings are difficult but the para-scientific events organized at the hitherto conventional pharmaceutical EUFEPS 2002 congress represents a valuable add-on which have the interest of the scientific community. Further refinement, marketing and sponsoring is needed before it is self-sustained, but the positive reception of the concept shows that it has come to stay.

2 Introduction

The methodologies currently available for the development of new medicines are unable to match the pace of drug discovery and design. Moreover the ever-growing demand for safety, efficacy and quality documentation has increased the cost and time involved in getting new medicines to the market. Although the pharmaceutical industry is one of the strongest in Europe in terms of research, innovation, exports and employment, there are severe limitations on reacting effectively to the challenge posed by the many regulatory demands to be fulfilled. This creates a conservative system, which tends to constrain the introduction of new faster techniques. Very few, if any, pharmaceutical companies can simultaneously work at their maximal speed to get new drugs through the development process, while also allocating the time and taking the risk for working with new faster systems.

Only through a pan-European approach involving industry, academia and regulatory authorities Europe can be prepared for the genomic challenge in drug development, thereby fulfilling the visions for the European Research Area (ERA).

During the last few years the number of stakeholders and players in research has increased considerably. The universities and academic scientists patent their discoveries and establish own companies to be able to pursue their ideas. This calls for financing and facilities to get started. The ethical issues of many of the new discoveries are serious and need to be addressed. The technology of development advances with ever increasing speed and the gap between the curricula taught at universities and the needs of the biopharmaceutical industries increases. This calls for postgraduate training courses.

The grants in the European Commission's Framework Programme increase in size, which in turn calls for improving the organisation of the active European researchers. Old networks originating from narrow scientific disciplines do not work any longer. Much broader networks are necessary and these must involve the new stakeholders.

Drug development represents an example of an integrated process *par excellence*. It has

- well-defined deliverables to the citizens
- interfaces with many scientific areas
- bottlenecks to be addressed
- the need for pan-European collaboration
- job generation potential
- room for start-ups and SMEs

What better opportunity could there be than using a multidisciplinary congress on the drug development process like the EUFEPS New Safe Medicines Faster congress in Stockholm 2002 to integrate the above-mentioned needs and create an "All-in-one congress" as a new concept and model for modern congresses?

Our vision was to create a new standard for scientific congresses of the future, thereby supporting the creation of ERA for drug development sciences, to be achieved through the following three objectives:

- Organise a first class scientific programme around the theme New Safe Medicines Faster.
- Gather around this core all the auxiliary disciplines and supporting organisations necessary to serve the needs of the participants regarding research industrial collaboration, ethics, training and education, job search and recruitment, entrepreneurship and start-ups finance and funding (including FP6 represented by the Commission) together with integration of press and public stakeholders.
- Assist the audience in a planned way to prepare and organise for networking and formation of integrated projects with regard to future applications for FP6.

3 Reporting

3.1 The main scientific congress

EUFEPS organized its biannual congress. Under the theme New Safe Medicines Faster This part was planned separately from the EU supported para-scientific add-on events, due to the uncertainty of obtaining financial support for the latter.

The meeting was held in Stockholm Exhibition Center and attracted some 650 industrialists and academics with a few regulators. The delegates were drawn from 37 countries (including many from outside Europe) with about 50% coming from industry.

The scientific presentations of the 2002 Congress were clustered around drug discovery and drug development processes, rather than disciplines. The topics were arranged in three major fields namely Drug Discovery and Design, Exploratory Drug Development and Human Drug Development. In a fourth stream Pharmaco-epidemiology and Genomics were in focus. The International Pharmaceutical Excipients Council (IPEC) and the European Co-operation in the Field of Scientific and Technical Research/Medical Research/Modeling during drug development (COST B15) contributed several sessions. The European Federation of Medicinal Chemistry (EFMC) provided speakers for one session, as did the European Association for Clinical Pharmacology and Therapeutics (EACPT).

For the precise topics and lectures please refer to the final programme attached as Annex 1. Independent of this report, short summaries of the four scientific streams will be communicated in the European Journal of Pharmaceutical Sciences.

The opening plenary session provided an interesting contrast between the approach to CNS drug delivery described by Professor Arvid Carlsson – intuitive, experience based and pragmatic and the Roche approach described by Dr Klaus Müller who stressed the need for ever increasing technological innovation in drug discovery. The

meeting felt that both approaches had merit and were perhaps more complementary than contrasting but Carlsson's examples of partial agonists showed that the most potent drug is not necessarily the best drug and that other factors may be as equally important as potency. Professor Hans Wigzell – head of the Koralinska Institute - gave a lively presentation on the activity of his institute whose 3000 scientists are undertaking no fewer than 11,000 projects. He picked out a non pharmaceutical project on working memory enhancement that is being achieved by the use of special computer games and the development of nicotine antibodies to illustrate the wide spectrum of activities. He also noted that 15 companies had already spun off from his institute.

It is always a benchmark of the quality of a conference if you as a delegate has difficulty in choosing which of several good concurrent tracks you want to attend. By this criterion EUFEPS 2002 was a success. The remainder of this report picks out a few highlights from the sessions. There were 3 full sessions; plenary and speakers, on excipients. This was clearly an important part of the congress and included presentations on topics such as:

- new excipients – inulin, cyclodextrin derivatives and startac captisol ™
- safety aspects – gelatin, residual solvents and metal catalyst residues
- regulatory aspects – regulatory, legal and industrial perspectives.

These sessions were sponsored by IPEC (International Pharmaceutical Excipients Council) whose newsletter and website (www.ipec.org.europe.htm)

Plenary Presentations

Dr Theo Guntert from Hoffman La Roche gave a very good presentation on the importance of "developability" in the selection of candidates to go forward to full development. He emphasized the need for early testing to be discriminating while predictive of potential future problems, especially with respect to specific organ toxicity in humans. He noted that there was fair, but not absolute, concordance between animal toxicity and human toxicity and noted that better model systems are currently under development. He also recommended concentration on absorption; metabolic stability, interaction potential and tissue penetration as important predictors of future problems. He noted that such tests may be of short duration but at relatively high doses. He also liked the idea of human testing at very low doses (microdosing) under a screening IND.

The rapidly evolving topic of computer simulation, of PK, PD and clinical trials was a theme that ran through the congress. Colin Pillu – a colleague of Jean Louis Steimer at Novartis noted that clinical trial modeling was only an extension of the well established techniques of PK modeling increasingly – in difficult areas such as cancer and paediatric studies. Among the benefits of modeling and simulation (M&S) he noted:-

- Optimisation of trial design especially with respect to biomarkers when efficacy is difficult to measure.
- Adverse event prediction.
- Easier dealing with non linear and variable response
- Facilitation of combining and bridging data

- Multiple indications
- As a predictive tool for back-up compounds.
- As a means of assessing chances of success.
- As a means of assessing competitive products.

He noted that the trend was to use M&S increasingly and that the FDA was not only accepting M&S as a tool at early stages but was using M&S techniques itself to evaluate NDAs. He said that there still lay challenges ahead notably in education of the wider drug development community and in the scarcity of good M&S scientists. However, M&S clearly can assist the NSMF concept.

In a dramatically contrasting plenary lecture Dr Arne Brodin a Director of Mgt Support in Pharmaceutical & Analytical R&D, discussed how formulation development of two old products, Xylocaine and Metoprolol has proceeded in Astra and subsequently AstraZeneca. He told a beguiling story of the search for new formulations to meet new needs and discussed the use of gels, sprays, patches, eye drops, mouth rinses and ointments. This was all to demonstrate how extra value can be generated even after a drug's patent life has expired. Although lidocaine discovered in the late '30s AstraZeneca has submitted a proprietary formulation NDA as recently as June 2002. Brodin emphasised that such value generation in a discovery based company was sometimes downplayed and that it needed a champion with the ability to sell his ideas and with abounding patience and perseverance. Again new medicines come about to the benefit of consumer and company alike.

In the next plenary lecture Professor Jan Lundberg, Head of Discovery Research described how AstraZeneca is facing up to the challenge of increasing the number of new drugs it is putting on the market. His opinion was that a global view was required backed up by local empowerment. He opined that economy of scale is achieved in large corporations in that they can balance the risk by having a wider and deeper portfolio of projects. Big companies alone can have the 700 collaborations that he reported AstraZeneca as having. He also said that companies must strive to achieve a balance between best in class against first in class. The first drugs rarely seem to be the best and are increasingly quickly being followed by similar but better compounds. He also said R&D must be humanised and said that only intra-company communication can achieve this. He also said that prediction of toxicity and safety is the biggest challenge and a key area in which to gain strategic advantage.

In the final plenary session, Carl Johan Dalsgaard, a partner in one of Europe's biggest specialist healthcare venture funds, spelt out the crisis of the industry. He said that Pharma has failed to meet its recent targets and felt that market expectation was at an all time low. Only innovative biotech companies offered hope for the future. They will, he claimed, be the great value creators of the future and feed big pharma who will increasingly become, in his words, contract development organisations for the biotech. This rosy picture for biotech will set against a backdrop of increasing biotech consolidation, with novel therapies spawning specialty, forward integrated companies so long as the biotech companies concentrate on their value drivers of science, intellectual property, access to highly motivated individuals and opinion leaders. Funding is available for biotech in Europe – they will become the drivers of pharma – or so he claims.

Speaker Sessions
The standard of the speaker sessions was in general very high. The presentations were pitched at the right level, clearly illustrated and, considering the majority were given in a foreign language, well delivered.

Franck Leveiller and Ruth Duncan addressed how covalently bound polymers can aid drug delivery and produce in one sense "nanomedicines" – contrasting to what Dr Müller said in his plenary that current drug discovery is largely on a micro-scale. Dennis Smith from Pfizer can always be relied on to give an interesting and challenging presentation. He backed up the call for more *in silico* modelling especially in the ADME area.

Following this lead Dr Schaeffer from Bushranger Ingelheim emphasised that good modelling can only come with input from chemists, clinical triallists, statisticians and particularly physicians.

Andy Grieve from Pfizer addressed the concept of adaptive design in clinical trials. In this scenario a computer assigns doses to patients based on the response of the previous patients – the computer unblinds the study while the study remains double blind to the supervising human staff. Peter Milligan also from Pfizer showed how modelling can reduce patient numbers while increasing statistical power.

A further speaker session dealt with prediction of drug metabolism based on early studies. The challenge of this area, exemplified in the talk by Nico Vermeulen from Leiden remains the prediction of turnover rates even if CYP450 affinities can be predicted with reasonable accuracy. It was interesting to see how a toxicologist PJ van Bladeren from the Nestle Research Centre viewed metabolism, using isoprene as an example which is a carcinogen in mice but not rats. Fortunately human metabolism is more like a rat's – but the mechanism he proposed was not predictive of carcinogenesis in mice either – so back to the drawing board for a convincing explanation.

In his discussion of proof of concept studies, Rainer Shulz of Quintiles drew distinction between surrogate markers (well validated biochemical parameters) and biomarkers (invalidated ones) drawing a further distinction between evidence of which we get much, and proof of which we, regrettably, have little.

Richard Jones from J&J commented that today much of early drug discovery is identifying drug candidates that are not drug like, and that this tendency is increasing. He felt the primary challenge for drug discovery will be the integration of knowledge with new technology.

Adam Cohen (from Leiden CHDR) gave a lively, if not very encouraging explanation of the lack of innovation in big pharma. His solutions include increasing R and decreasing D by killing drugs in development earlier.

The final speaker session addressed human and animal models in CNS disease. Professor Olivier described his mutant, anxious mouse while Søren Sindrup discussed

how human pain models could distinguish codeine from imipramine in a neuropathic pain model.

Summary
The process oriented presentations were very well received by the audience. They seem to be a logical and straightforward way of presenting the themes and topics of such a congress. The balance between the many areas that constitute drug development was also reached since all major themes were there. At the same time the mixture between academia and industry was optimal. Many attempts to make the development process safer and faster were presented. Indeed it is possible to shorten the process but much more integration and knowledge management is necessary. In this connection it has been interesting to see from very many lectures at the congress how modeling and simulation has been taken up with the purpose of better prediction. It is anticipated that this will be one of the areas of real expansion in the future.

3.2 Afternoon Specials

Over recent years, many small and now medium sized enterprises (SMEs) have been established. More of the discovery process and support to drug development seems to take place in small research units. Clinical development, scale-up and regulatory matters remain in the hands of bigger companies. Regulators approve all new medicines for the European as well as the global market.

Whatever the setting, collaboration will be needed with a number of stakeholders, e.g. private and venture capital investors, training, education and health-care providers, national and other funding bodies, equipment suppliers etc. Also important are ethical considerations, job searching, and start-up advice and so on.

In the EUFEPS 2002 Parallel Afternoon Specials, new and hot issues was discussed and debated. Below the reports describing the content and outcome of each of the sessions are given.

3.2.1 EU 6th Framework Programme: Its basis and its pharmaceutical impact

Co-Chairs *Ole J Bjerrum*, Copenhagen DK; *Alfredo Aguilar,* Brussels BE

Objectives
The session will convey an understanding of the thinking behind the programme in general and the pharmaceutical sciences in particular vis-à-vis the New Safe Medicines Faster initiative and Expressions of Interest the Commission have received.

The target audience was potential applicants for grants under FP6. The session gathered 60 participants.

Programme
- Drug discovery in the EU Framework Programme 6 (FP6).
  Alfredo Aguilar, Brussels BE

- New Safe Medicines Faster and FP6. New opportunities for the pharmaceutical sciences.
  Ole J Bjerrum, Copenhagen DK
- Results of the Expression of Interest with emphasis on those related to pharmaceuticals.
  Thorbjörn Ingemansson, Brussels BE
- Questions and Answers Panel

Outcome

Dr. Alfredo Aguilar, EU Commission, emphasized the position of the pharmaceutical industry as one of Europe's best performing high-technology growth sectors covering 560.000 jobs of which 88.200 were in the R&D units. It created €25 bio in trade surplus in 2000. However, the competitive edge of Europe is declining. Thus the origin of the top 10 medicines by worldwide sales dropped from 6 to 2 of European origin from 1992 to 2000. Through research funding of €1100 mio for advanced genomics and its application for health, the Commission wishes to strengthen the research base for this sector in Europe. One of the ways is through technological platforms covering integrated multidisciplinary research which should deliver health-care progress, increased quality of life, cost reduction, precise diagnostics, individualized treatments, new drugs and therapies, novel products from genomics and biotechnology to the society.

Professor O. J. Bjerrum, The Royal Danish School of Pharmacy, gave a survey of evolvement of the EUFEPS initiative New Safe Medicines Faster and how the interaction between EUFEPS and DG Research has developed. He took the appearance of the many similarities between the New Safe Medicines Faster initiative and the final text regarding the pharmaceutical aspects in the work programme as proof that the Commission indeed had listened to EUFEPS's proposal. He used this to exemplify how open the Commission is for new thoughts in the interest of European scientists. He also emphasized the unique opportunity the present work programme gives the pharmaceutical sciences in Europe to become revitalized to meet the global competition. His last words were: "The topics are there. Be ambitious and go for them."

Dr. T. Ingermansson, EU Commission, explained the reasons for the invitation to submit Expressions of Interest (EoI) which were to identify priority topics, to focus the call, to avoid over-subscription, to assist in proposal making and to assist in consortium building. In all 2000 EoI's was received of which 127 topics were selected. Priority 1 contains biotechnology, applied genomics, therapies, diagnostics and rationale for accelerated development of new, safer and more effective drugs. In the last group following topics of specific interest for the pharmaceutical sciences were selected: Computer assisted modeling for drug discovery and clinical trial; blood substitutes; genome based individualized medicines; novel therapies for neurodegenerative disorders; genome-based anti-psychotic therapies; signal transduction pathways as targets for disease detection and treatment; development of medicines in paediatrics; antiviral therapeutics; new drugs from novel sources; in-vitro alternatives to animal and human toxicology testing; application of in-vitro methods.

The audience praised the new programme especially noting that there was money reserved for unpredicted projects. Many specific and concrete questions from the audience closed the session.

3.2.2 Innovation and New Chemical Entities (NCE) development

Co-chairs *Giovanni Gaviraghi*, Siena IT; *Jörgen Vessman*, Mölndal SE.

Objectives

This section is aimed to discuss from scientific, industrial and financial points of view the dramatic changes in the pharmaceutical drug discovery process which have taken place in the last decade.

The Target audience was industrial and academic researchers and managers and financial experts. The session gathered 75 participants besides the speakers.

Programme

- Overview of the discovery process in the 90's.
  Giovanni Gaviraghi, Siena IT.
- The productivity of the new drug discovery process within the industry: Challenges and perspectives.
  Robin Carr, Cambridge UK.
- Development of NCEs - Related criteria and analytical determination.
  Patrizia Ghiotti, Verona IT.
- Panel Discussion
  Chaired by *Jörgen Vessman*, Mölndal SE.

Outcome

Dr. G. Gaviraghi, Siena biotech, gave a short introduction, where he focused on the change in the paradigm for drug development: He explained that this was from one based on combined pharmacology and chemistry via a disease model to one based on gene expression and disease via target and screening followed by combined chemistry and pharmacology. He emphasized the fast growth of target discovery at the end of the nineties but also the tremendous value of an identified lead provided the target was disease related.

Dr. R. Carr Astex gave an excellent overview of the present situation regarding productivity in the new drug discovery process. The number of New Chemical Entities (NCEs) being registered is decreasing, while costs are greatly increasing. The attrition rate is high and about 50 % both in the preclinical stage and in clinical phase 2. The evolution of High Throughput Screening (HTS) is illustrated by a 100 times increased rate from year 1992 to 2002, but it represents high speed rather than high efficiency. He also stated that 75 % of the targets screened do not give high quality hits and more than 80 % of leads from HTS are weak and do not survive 6 months. He advocated a knowledge based approach, where the selection and not the number on the scale is critical, since with random sampling anyhow only a tiny fraction of the 10^{40} compounds in the drug-like space are covered. Furthermore, Dr. Carr a drug-like compound as a lead will often end up in a less drug-like one regarding molecular weight and metabolism after lead optimization. It is then preferable to start with a simpler fragment of a structure in order to make a drug-like molecule. He suggested

libraries of a size of 500-1000 compounds. He concluded by saying that the greatest barrier to success in drug discovery is the lack of understanding and communication between different areas of specialization.

Dr. P. Ghiotti, GlaxoSmithKline Italy, focused after a brief overview on NCE development in terms of processes, costs, timings and milestones, on the candidate selection process as crucial for saving both time and money. The so-called "developability criteria" are aimed at assisting the selection process so as to choose the most promising compound to be progressed. Even though such criteria have been established for all the R&D disciplines, the lecture concentrated on those physico-chemical criteria that have greatest impact on the pharmaceutical development of the molecule. These have been split in two categories, one pertaining to the preferred compound profile and the other to the minimum acceptable profile. Since the criteria are specific to the route of administration, the most common ways of administration, the oral and the parenteral, were considered.

In the following discussion Dr. Carr commented that high throughput screening (HTS) is being less "hyped" today but is still useful. He also said that the instrument companies are the winners and that miniaturisation saves reagents but is difficult. Once more he overall advocated for a knowledge based NCE process.

The availability of scientists with the right skill in Europe is very important for the region to stay competitive in the global arena. The lack of toxicologists was brought forward as an important impetus to move laboratories to US because of the broader access to people skilled in this discipline there.

3.2.3 Training and Education I + II

Co-Chairs *Bernd Clement*, Kiel DE; *Fritz R.. Bühler*, Basel CH

Objectives
There is an increasing gap between the needs of the pharmaceutical industry and the output of academic institutions, with respect to the training received in academic programmes. So there is strong support for pan-European post-graduate training programmes in pharmaceutical sciences to fill this gap. In two sessions surveys on existing models and further initiatives will be presented and discussed.

The target audience was post-graduate students and all other involved in training and education. 28 and 16 persons represented the audience in session I and II, respectively.

Programme and speakers at session I
- Postgraduate education for pharmaceutical scientists (EUFEPS´ model and other)
  Bernd Clement, Kiel DE
- European pharmaceutical education – a new programme
  Fritz R. Bühler, Basel CH
- Postgraduate education of medicinal chemists (International Quality Network – Medicinal Chemistry and others)
  Bernd Clement, Kiel DE
- Discussion

Programme and speakers at session II

- The "ULLA" Model
  Birthe Jensen, Copenhagen DK
- GALENOS Network and European Masters Program in advanced drug delivery
  Daan J. A. Commelin, Utrecht NL
- Drug Regulatory Affairs – a master course
  Richard Süverkrüp, Bonn DE
- Discussion

Outcome

The focus of the two afternoon specials was the increasing need in the pharmaceutical industry for academics who can cover the broad areas of the total drug development, and the European initiatives to meet these needs. Very different models with different scopes were presented and elucidated.

It was evident from the presentations that no courses could cover all kinds of needs. It is, however, a problem, that it is nearly impossible to get a reliable overview of existing courses and programmes.

Definitions of "Post-graduate" and of "Master Degree" were subject for a thorough discussion. As the 3 + 2 education system is being adapted all over Europe the first degree is obtained after three years, "Post-graduate" will become "what is after the first three years". This is not the current use of "post-graduate" in most countries, as the first degree now normally is obtained after a curriculum of 4 or even 5 years. A corresponding confusion exists for the concept "Masters Degree". This can be the result of the last two years study of a five-year curriculum. But it can also be a separate second degree obtained by further studies *after* the five years. Thus a clear and generally accepted definition of the magnitude (length etc.) of a Masters-curriculum is needed.

The confusion adds to the difficulties in getting an overview of courses and programmes relevant for employees in industry, as some universities announce "Master Programmes" separately while other universities consider corresponding activities as an integrated part of a one-tier curriculum. Furthermore, only few universities actively announce courses primarily created for PhD-students which could be of value for external participants.

The GALENOS Network had circumvented the mismatch concerning titles and content by introduction of a "EUROPEAN POSTGRADUATE DIPLOMA" (EPD). This may be a way forward for groups of collaborating high quality networks and for EUFEPS, as the Diploma will gain respect from the quality of the programme.

Conclusions

Following points need a "European" solution: Generation of a database on existing European courses and programmes. Clear definitions of what "post graduate education" and "Masters Degree" cover. A suggestion brought forward was introduction of European postgraduate diploma: EPD.

3.2.4 Ethical aspects in drug development

Chair *Lars Reuter*, Aarhus DK

Objectives

The development of new medical drugs takes place in an environment of diverse and often competing interests between consumers, producers, and lawmakers. Typically, freedom of research and the protection of the individual human being are seen as the two hallmarks guiding European policies on this development. This panel will explore possibilities and problems in this regard.

The target audience was R&D staff in general. The number of participants in the audience was 26.

Programme

- Freedom of research and protection of the individual in a European perspective
  Lars Reuter, Aarhus DK
- Specific problems related to drug development
  Ron Bergmans, Maastricht NL
- Fundamental issues raised by drug development
  Sven Andersen, Aarhus DK
- Questions and Answers Panel

Outcome

In view of the considerable costs of some biotechnological procedures and the often heated debate about certain techniques, e.g. related to the use of human stem cells, it is vital to assess the ethics of new products and techniques as early as possible in the process. This means that ethics is part of the R&D process. In line with these thoughts, ethicists, i.e. specialists trained in ethics were invited to meet an audience of pharmaceutical scientists at the EUFEPS 2002 conference. The idea was to demonstrate the significance and impact of ethics as a discipline in the pharmaceutical R&D process.

The concurrent session focused specifically on ethical aspects of drug development. Professor L. Reuter, Centre of Bioethics, Aarhus University, spoke of the ethical and legal framework that sets the stage for new drugs. Professor S. Andersen, Centre of Bioethics, Aarhus University then described the foundations of ethics, stressing central motifs in ethical deliberation. Professor R. Bergmans, Department of Health Ethics and Philosophy, University of Maastricht reflected upon the protection of vulnerable patient groups in research and the responsible development of drugs, with a particular focus on patients suffering from Alzheimer's disease and the tension of respecting informed consent while assuring the further development of medication related to it.

The workshop facilitated a very stimulating interaction with the scientists attending it. The persons present engaged themselves in a lively discussion about the relevance of ethics in R&D, with special attention to the notions of “(informed) consent” and “foundational values”. In this respect, the workshop did achieve one of its major goals, namely to raise awareness of the role of ethics in the development of new drugs.

This experience, together with the positive attention it received in general, both led to the suggestion that similar workshops should be included in future EUFEPS conferences. Furthermore, they emphasize the significance of such interdisciplinary cooperation, which should be sought also on the institutional level, e.g. between EUFEPS and the European Ethics Network (EEN). Such cooperation is now being implemented.

3.2.5 Scientific east-west integration in Europe

Co-Chairs *Pia Vuorela*, Helsinki FI; *Sándor Görög* Budapest HU

Objectives

New countries are entering EU and the activities to join e.g. the EU 6th Framework Programme are in full swing. The tool for successful integration of academia, research and pharmaceutical companies in a fast way needs to be evaluated. This session explores possibilities, problems and progress in this respect.

The target audience was potential persons for cooperation and networking. The session gathered 34 participants.

Programme

- Research and development strategy in a recently privatized pharmaceutical company in Central/Eastern Europe
  Gábor Blaskó, Budapest HU
- Cooperation of universities in central and Eastern European countries with western institutions
  Alès Mrhar, Ljubljana SLO
- What are the possibilities for the integration in Europe?
  Peep Veski, Tartu EE
- Panel discussion

Outcome

Professor G. Blaskó, Research Director at EGIS Pharmaceuticals Ltd., presented his company, the history and present strategy: This is to renew the Company's product port folio via generic development and discovery research, collaborative research with Servier on the fields of chemistry and pharmacology, having its own preclinical development and with clinical development being conducted by Servier. The turnover is $40 mio and R&D expenditure represented 7-8% of current sales with good candidates in the pipeline. Thus EGIS is can example of an SME with a promising future.

Professor A. Mrhar, Department of Pharmacy, University of Ljubljana, Slovenia, discussed the principles of scientific east-west integration in Europe on the basis of 2 questions: Do University graduates in Europe meet the needs of 1) The pharmaceutical system, 2) The healthcare system?

Regarding the first question the disciplines required should be studied on a basis of a multi-disciplinary approach rather than in isolation. Information and communication technology should be utilized for speeding up the drug development process. Thus the universities must strengthen these disciplines in their curricula so as to fulfill the

needs of the pharmaceutical industry. As answer to the second question since pharmacists are part of the healthcare providers' team, WHO has summarized the role of the pharmacist in seven essential areas. The following disciplines appear to be relevant: clinical pharmacy/pharmacovigilance, pharmaceutical communicology, pharmaceutical law and ethics, pharmaceutical management, pharmaceutical regulation, pharmaceutical statistics, pharmaceutical informatics, pharmaco-epidemiology, pharmacoeconomics, pharmaceutical marketing along with or as a part of pharmaceutical care as a backbone of patient oriented pharmacy. It is ultimately for the schools of pharmacy to introduce these disciplines in their curricula besides natural, biomedical and other pharmaceutical sciences to so that pharmacists can get and hold positions in the healthcare system.

The main problem the pharmaceutical professionals and scientists in Central/Eastern European countries are facing is the fact that these are new and small-sized states. Viewed from global perspective the nations are not thought to possess considerable potential in the fields of pharmaceutical sciences and technologies. Consequently, the results of their work are not widely recognised and therefore the transfer of know-how is difficult. What they presently need is access to institutions (faculties, institutes, industries) with first rank educational and scientific programmes to get contact with well trained scientists and professionals in academia and industrial enterprises. The instruments to promote these activities would be invitations, exchanges, fellowships and information links, internet and library networks. Inclusion of pharmaceutical education and research programmes in the international collaboration projects such as PHARE, SOCRATES, EU FRAMEWORK PROGRAMMES, COSTS, and bilateral-twinning projects within the region and between the partners in the region with those in European Union, are not only exceedingly welcome but are critical.

The responsibility for the success of this process ties both the eastern and western side. The eastern side has to make the efforts to fulfil the criteria that are needed to implement the common principles in their systems. The western side is expected to recognize eastern institutions as partners able to contribute significantly to further progress of the pharmaceutical sciences in Europe.

Professor P. Veski, Department of Pharmacy, University of Tarttu, spoke about scientific East-West integration in Europe limited to the science of pharmacy. To realize the idea about European Research Area, which is planned to take conclusive shape by the year 2006, serious efforts are made at the level of the European Union as well as at the level of professional federations and associations, including EUFEPS. The prerequisite for the realization of the idea is the preparedness of East and West for cooperation. The Western European readiness is often mistakenly identified with the impressive amounts of money proposed in the framework programmes. A much more important prerequisite is the will/wish. This wish should be in every potential cooperation partner from Western Europe.

What are the factors influencing the possible cooperation on which the Eastern European institutions' research depend? The factors that influence the current level of the Eastern European institutions that are willing to obtain integration in the European Research Area and cooperate as equal partners, are the following: pharmacy is considered among the priorities of a country; the critical number of scientists; the speed of economic and social reforms; historical background (traditions); and

motivation and preparedness of specialists working in the fields of pharmacy. It should also be noted that the development of pharmacy depends on the existence of a pharmaceutical industry. Countries that have willingness to obtain integration in the European Research Area have to undertake activities such as legislation, development of infrastructure and local financing of science that could help to increase the motivation and qualification level of scientists.

Finally Dr. P. Vourela, Drug Discovery Technology Center, University of Helsinki, reported on some recent initiatives on student exchanges. The Finnish Ministry of Education through the Center for International Mobility, CIMO, together with the Finnish higher education institutions, should devise a marketing strategy with special emphasis on cooperation with Russia and with Central and Eastern European and Asian countries. The regulations governing students' entry and residence in Finland should also be made more flexible. A big problem is that very little teaching is given in English at institutions. Furthermore the content of pharmaceutical disciplines is changing. Interactive discussions on common principles are needed under the supervision of EU.

Conclusions
The tools for successful integration of academia, research and pharmaceutical companies were rapidly identified to be: 1) Personal contacts 2) Readiness and willingness (on all levels personal, governmental, educational, industrial etc.) and
3) Efficient student exchange (contacts should start when people are young!). A need for individuals who would be interested to work for this was identified. Associations like EUFEPS and the Fédération International Pharmaceutique (FIP) may be instrumental in the process.

3.2.6 EU 6th Framework Programme: Specific instruments and measures. Practicalities and relevant examples

Co-Chairs *Alfredo Aguilar*, Brussels BE; *Ole J Bjerrum*, Copenhagen DK

Objectives
The objective of this session was to convey an understanding of the intentions and contents of the new instruments, together with practical hints for the organization of consortia and professional management. Many other funding possibilities of the FP6 for the pharmaceutical scientist will also be presented. The money allocated for training and education are doubled in FP6 for which reason examples of successful training programmes in large scale from FP5 are presented.

The target audience was potential applicants for grants under FP6. The session gathered 20 participants.

Programme
- New instruments for thematic priorities: Networks of Excellence and Integrated Projects.
  Alfredo Aguilar, Brussels BE
- Additional funding possibilities and practicalities: Specific targeted research and innovation projects, specific research projects for SMEs, training and education,

co-operation frameworks, joint initiatives with scientific organizations, co-ordination actions, research infrastructures.
Thorbjörn Ingemansson, Brussels BE

- EU Training grants: Experience from FP5 on courses in big scale (> 1 mio Euro)
  Heather Marshall-Heyman, Stockholm SE
- Lesson to be learned from courses of the genetic basis of disease.
  Mikael Holst, Stockholm SE
- Questions and Answers panel

Dr. A. Aguilar, EU Commission, emphasized the importance of successful projects developing multidisciplinary research programmes through integration of biology and technology, technology producers and technology users, stakeholders (extended audiences), small and medium sized enterprises in the projects, and innovation and exploitation. The multidisciplinary aspects are obtained through cutting across S&T disciplines, approaching lateral issues and interfaces between disciplines. The research projects may include basic, applied research, demonstration activities provided that it is transnational research with clear deliverables and basic knowledge being applied, it addresses major societal needs, and it increases EU competitiveness. He closed the lecture by giving all the internet addresses for the needed information about FP6 to be ready to apply when the first call for proposals appear 17 December 2002.

Dr. T. Ingemansson, EU Commission, visualized how FP6 will build on FP5 achievements with its 10000 proposals, 1800 funded projects with participation of 1400 laboratories, 1200 individual fellowships and the created infrastructures: Industrial platforms, EuroBiobiz and Biotech Finance Forum. The positive tend for the Biotech industry in EU versus US should be continued. It is noteworthy that FP6 represents a shift in strategy as the support to small and medium sized companies increased from €1100 mio to €2100 mio. Thus the exploitation-innovation cycle will be supported with 25% to the science base, 25% to the innovation culture (IPR, know-how and awareness) and 50% for commercialization (entrepreneurship, business plan, financing and public perception).

Dr. H. Marshall-Heyman, Karolinska Institute, Stockholm, described how her institution has exploited FP5 to get a training grant of about €1.5 mio to set up a European consortium consisting of 7 universities for arranging postgraduate (doctorate) courses. The lead time from concept to application was 10 months. The grant has given rise to 45 general and 65 special courses together with 70 specific research projects for the involved students.

Dr. H. Marshal-Heyman closed her lecture with the following advice to future applicants:

- Do not diverge too far from your own and your organizations' areas of interest.
- Find common areas of interest between yourself, your European and other international colleagues, and the EU.
- Think around your subject: what is its impact, who will use the results; what implications does it have on a wider EU scale.

Dr. M. Holst, Karolinska Institute, Stockholm who has the responsibility as organizer for the courses, followed up the lecture. He summarized the lessons to be learned as follows:

- If possible, plan courses in close connection to established conferences, e.g. as Summer Schools, etc.
- Invest major effort into information and advertisement, including posters.
- Do not underestimate costs for information and service to course participants.

3.2.7 How to promote innovation and science driven regulation?

Co-Chairs *André Broekmans*, London UK; *Maj-Inger Nilsson*, Brussels BE

Objectives

At this moment the future medicines legislation is under debate in the European Parliament and in the Council. The proposals of the Commission will have important consequences for Research and Development within the European Union and the patient's access to innovative medicines. Do the proposals really foster the innovation in Europe and are decisions by the CPMP really science driven? The session will deliver new building blocks for the discussion.

The target audience was R&D staff, regulators and health care professionals. The session gathered 42 participants.

Programme

- Perspective from the EMEA
  Bo Aronsson, London UK
- Perspective from a national authority
  Gunnar Alvan, Uppsala SE
- Safety evaluation of drug candidate: Barriers to development or benefit to their safe use.
  John Caldwell, London UK
- Perspective from industry
  George Butler, Alderley Park UK
- General Discussion

Outcome

Assoc. Professor M.-I. Nilsson, Pharmacia, opened the session by pointing out the schism between the wish to see many new innovative drugs and rigid regulatory demands.

Dr. B. Aronsson, European Medicines Evaluation Agency (EMEA), was presenting the views from the EU Regulatory body, with special emphasis on the Scientific Advice procedure and the improvements proposed. Figures from EMEA are indicating that the numbers of drug applications are dropping quite dramatically this year. Tthis is also true for the FDA. For the EMEA this will have budget implications.

Professor G. Alvan, General Director of Swedish Medicines Agency, presented the national perspectives. With a science background he took a little broader perspective on how to promote innovation and science driven regulation. He proposed to:

- work with science and evidence based evaluations as gold standards
- use scientific principles for consistent and sustained drug development
- promote scientifically driven risk management for safety precautions
- be prepared to withdraw scientific requirements that have become obsolete
- recruit competent people to the regulatory agencies
- let competence meet competence in exchanges between the pharmaceutical industry and regulatory agencies
- have friendly coexistence with other systems.
- rely on democratic principles
- stimulate promising therapies from the natural remedy domain to undergo scientific work and evaluations.

Professor J. Caldwell, Dean of Faculty of Medicine, University of Liverpool, focused on the major issues of safety evaluation of drug candidates. It seems that the failure to manage attrition during development is linked to an enforced withdrawal of approved drugs from the market today. This has focussed much effort upon the development of appropriate biomarkers and other easily detected early surrogates for major toxic effects, following the example of the Ames test for mutigenicity as an indicator of mammalian carcinogenicity. While this work is extremely important, few, if any of these tests are sufficiently established at present to be of real use for regulatory purposes. For example, drug-induced cardiac arrhythmias, which may be life threatening, have led to the withdrawal of at least 1 drug per year over the past 15 years. In response, a series of electrophysiological tests, have been proposed as preclinical surrogates. However, there is a large number of both false positives and false negatives with these tests which makes these tests poor surrogates of human toxicity. Nevertheless, attitudes within drug companies and emerging regulatory guidelines alike show that what was intended to be a preclinical indicator of a potential human toxicity has now become “toxicity” in its own right.

The problem of drug withdrawal from the market is largely an issue of rare and/or unexpected toxicity. There are many examples of drugs with serious and life-threatening toxicities, which are nevertheless effectively managed. In these cases, due weight has been given to preclinical findings and their market introduction was managed with caution, encouraging good prescribing to optimise risk/benefit and allow effective management of any human toxicity.

Dr. G. Butler, AstraZeneca, representing the industry has been working in the Regulatory business, both in Europe and the USA for many years. Dr. Butler discussed the likelihood that the "purchaser and the patients" needs, will become a more dominant feature of drug development and availability. This will generate benefits such as: earlier availability of new treatments to patients; better risk management (including human safety) and faster take up of better treatments (already "real world" test).

Conclusion

The outcome of the discussion was that effective drug regulation requires a sound scientific basis. It is important that new guidelines addressing new emerging issues strike a balance between adequate validation and the protection of the public, without stifling the creativity inherent in drug discovery and development. Overall, there seems to be an excellent climate for partnership between the Regulatory agencies,

Academia and the Industry. Further steps will follow to capture this, also involving patient organizations.

3.2.8 Biotech innovations and SMEs does it smarter and faster

Chair *Claes Post*, Stockholm SE

Objectives

Drug discovery productivity has been defined as an area, where the large pharmaceutical companies have a problem. With this, the industry anticipates that the smaller innovation-driven companies will play an important role in filling the project gaps. It must not be forgotten however that drugs emanating from the small companies need to fulfil the same criteria as those generated from the larger companies in terms of data quality, and compliance with regulatory requirements. If a smarter approach is applied within the Biotech and SMEs, it must therefore be combined with the same strict project criteria as those applied within the large companies. The overall objective of the session is to discuss approaches to drug discovery within the smaller research companies, and how to match the requirements for quality and innovation. The session will also address the issue of interfacing start-up companies with the venture capital, academia and Contract Research Organizations (CROs).

The target audience was scientists and managers from Biotech and SMEs, scientists from academia and people from venture capital firms. The session gathered 31 participants.

Programme

- Introductory remarks
  Claes Post, Stockholm SE
- Innovation driven drug discovery and development
  Björn Nilsson, Stockholm SE
- Academic-company interfaces and Contract Research Organisations (CROs)
  Daan Crommelin, Utrecht NL
- General Discussion

Outcome

This session focused on the interaction between “Biotech companies” (as therapy oriented drug discovery companies, the Venture Capital Industry and Contract research organisations.

Professor C. Post being partner at Danske Life Science, introduced the sessions by giving his view on the Biotech market, and in particular the Nordic. This is a region within the EU, plus Norway, which has a large number of Biotech companiesthe region has the highest number of biotech companies per inhabitant in Europe.. He predicted that there would be considerable consolidation because of their large number, their small size and the limited amount of venture capital. This will create larger units with hopefully obvious synergies. Meanwhile, it is expected that new companies will continue to be formed and later to be going into the consolidation phase, provided that innovative ideas and capital will continue to be rich in the Nordic region. The industry is here to stay.

From a business point of view, the companies are strongly needed in the global health care industry, since productivity among the Big Pharma companies is below what is needed for their sustained growth. All Big Pharma companies claim that they intend to introduce 3 – 5 new drugs onto the market per year, but currently only introduce one product about every second year.

Professor B. Nilsson, CEO of KaroBio, presented his company and how it has developed in terms of projects in pipeline and external collaborations. KaroBio is a drug discovery company that intends to take their projects up to proof of concept in man, and to make deals with Big Pharma companies to develop the projects through the costly and time-consuming later clinical development and marketing. KaroBio has a number of deals with leading companies, and the projects today deliver up-front and milestone payments to KaroBio, later to be followed by royalty streams from products sold. KaroBio is pragmatic as to when a deal should be closed with Big Pharma, in that the ongoing collaborations today have been entered already in the preclinical phase. The background to this is the world leading knowledge in the company's research in intracellular nuclear receptors. This has created the effect that the company collaborates in a number of medical areas where nuclear receptors seem to play an important role.

Professor D. Crommelin is a founder of Octoplus, a contract research organisation. Octoplus has been set up to be self-financed, based on incomes from services to a number of companies. He noted that the market driver for setting up the organisation was that most SMEs and Biotechs have limited pharmaceutical development expertise. His personal objective was to help bridge the gap between academia and industry while making money, creating jobs, and commercializing technology. He felt it was a fine challenge and an opportunity to learn. He emphasized the importance of human factors to success: trust, commitment and recognized that jealousy must be overcome. The founder of enterprises like Octoplus must be optimistic, energetic, patient be able to make sacrifices and to accept rejection and be an aggressive networker.

The following discussion stressed the strong collaboration between Big Pharma, Drug Discovery companies, Contract Research organisations and Venture Capital companies. Furthermore, it was apparent that there are no country barriers to this, in particular within the EU. Given the need for new drugs to be introduced on the market, both from a societal and Big Pharma point of view, these alliances are here to stay, and they will continue to generate novel job opportunities, as well as and interesting place for Venture Capital financing.

3.2.9 Pharma/public interface: "Dialogue with the public"

Chair *Jens Degett*, Strasbourg FR

Objectives

Though we always hear how important it is to communicate science to the public many scientists are reluctant or even afraid of talking to the media about their research. This fear is not without reason, as there are many examples of how information has been misunderstood or misused by the press. Communication

strategies and advice will be given on why and how to communicate with the public illustrated with examples from the real life.

The target audience was scientists, science administrators, communicators. The session gathered 16 participants.

Programme

- Perils and prospects of communicating with the public
  1. The importance of communication
  2. Real life examples on good and bad communication
  3. Communication strategies how and why?
  4. General advice on communication, ethics and rules.

  Jens Degett, Strasburg FR and *Bo Øksnebjerg*, Bagsvaerd DK
- Final discussion, questions and answers

Outcome

The journalists Jens Degett from the European Science Foundation and Bo Øksnebjerg from Novozymes, a major Danish biotech company, conducted this very interactive session.

Communication strategies and advice was given on why and how to communicate with the public illustrated with examples from the real life. The fundamentals of communication were presented by 40 PowerPoint slides supplied by two video examples specially designed to this presentation. These examples gave some good impression on good and bad ways of communication. The first video compared a small film made by Novo Nordisk (Denmark) with a film from CNRS (France) on animal experiments. These films spoke for themselves and were very illustrative on how differently such presentations can be made. The other video showed two interviews from a Danish television programme, where two medical doctors are asked the same critical questions. The first one is well prepared, and the second doctor needed some media training - unfortunately for him the journalists show all his reactions starting with a 15 second thinking break, and then all the excuses which finally leads to some answers.

The two video examples were subtitled in English and illustrated the importance of being prepared. The participants in the session responded well with examples from their own laboratories or companies and advice was given on how they should tackle these situations in the future. The key messages on the importance of communication and the importance of being proactive when working with controversial issues were well received by the audience.

3.2.10 Future role of European scientific associations

Co-Chairs *Dominique Duchêne*, Paris FR; *Malcolm Rowland*, Manchester UK

Objectives

One of the major objectives of EUFEPS is to advance research in the pharmaceutical sciences in Europe. This can be achieved by promoting cooperation between national, regional, and European societies or associations, which aim at the advancement of pharmaceutical sciences and by promoting cooperation between and with other

pharmaceutical organizations. How to move from the official wish of EUFEPS to reality? How to make European pharmaceutical sciences a partner in the world scientific competition? This will constitute the backbone of our discussions.

The Target Audience was representatives of European pharmaceutical sciences societies, scientists and students in pharmaceutical research. The session gathered 18 participants besides the speakers.

Organizations and associated speakers at the sessions:

- EUFEPS (Professor Dominique Duchene, President)
- European Federation of Medicinal Chemistry, EFMC (Professor Henk Timmerman, President)
- International Society for the study of Xenobiotics, ISSX (Professor Nico Vermeulen, President)
- Pharmaceutical Sciences Section, Slovenian Pharmaceutical Society, a small member society (Dr.Uros Urleb)
- Spanish Society of Pharmaceutics and Pharmaceutical Technology, a new specialized member society (Professor Angel Concheiro-Nine, President)
- Association Pharmaceutique et Galenic Industrale, APGI (Professor Dominique Chilia)

Outcome
The main purpose of this session was to explore ways in which European scientific associations could collaborate better on the advancement of the pharmaceutical sciences within Europe, as well as make Europe a stronger partner in the world scientific community.

Professor D. Duchene, Dept. of Pharmacy, University Paris Süd, identified what EUFEPS sees that it can do for its members as well as throwing out the challenge as to what member societies could do to make the vision into a reality. The idea of the establishment of a Pharmaceutical Fair in 2005 was presented, envisaging how scientific associations would come together at one place (Nice, France) and time to exchange ideas and explore ways of improving collaboration, each society (or a collection) would organise a scientific program. A promising start had been made with 22 organisations responding to the first call.

Professor H. Timmerman, European Federation of Medicinal Chemistry (EFMC), stated that the federation has been in existence for some 30 years, currently comprises 20 member societies (8000 total members), and has been primarily concerned with organizing biennial international symposia in medicinal chemistry. It was proud of its directory of medicinal chemistry comprising a description of each of its member societies together with a list of European manufacturers and suppliers of products and services for medicinal chemistry. It has recently started to collaborate with EUFEPS.

Professor N. Vermeulen, International society of the science of Xenobiotics (ISSX), representing this international organization comprising some 2500 individual members in over 50 countries. He stressed that pharmaceuticals were only one, albeit important class of xenobiotics, others including food additives, pesticides and environmental pollutants. By virtue of being international ISSX has a global interest,

but the European members are significant in number. It was interested in interfacing with EUFEPS.

Dr. U. Urleb, Slovenian Pharmaceutical Society, stressed that the major interest of his society was the maintenance of an adequate supply of well trained graduates in the pharmaceutical society to meet its growing industrial needs, and that these graduates should understand and feel comfortable with the multidisciplinary nature of the subject. Among ideas where EUFEPS might help to improve the situation still further were: Promoting pharmaceutical sciences; motivating high quality students to take postgraduate courses in pharmaceutical sciences; provision of training courses, meetings and congresses in drug discovery and development. Another important role of EFUEPS was to promote scientific cooperation between industry and academia, particularly breaking down barriers between different areas of specialization as well as improving the melding of these, to facilitate better research and innovation.

Professor A. Concheiro-Nine, Spanish Society of Pharmaceutics and Pharmaceutical Technology, had some 150 members, mainly from academia. Attention was directed to increasing the awareness and membership of the society within industry. It looked to EUFEPS to assist his own members to become increasingly involved in various European scientific activities, such as FP6.

Professor D. Chilia represented a EUFEPS Member Society (APGI) on the pharmaceutical sciences, pharmaceutics and pharmaceutical technology. Although with a small membership of some 250 scientists, located in France, it sees itself as an international association. It strongly supports the concept of the Pharmaceutical Fair, which it saw as both an opportunity to profile the activities of its membership, but also to collaborate with others in promoting both its own speciality as well as the pharmaceutical sciences within Europe.

Conclusion
Overall, the participants of this session agreed that much has been achieved in the past and that more integration is expected in the future with EUFEPS as an important player. The Pharmaceutical Fair could well serve as a forerunner of unique European structures that would further ensure increased collaboration among pharmaceutical scientists within Europe.

3.2.11 Conclusion on the concept of the Afternoon Specials

The format and most of the topics must be considered as a success judged by the size of audiences and the lively discussions. Taking in consideration the time of the day the number of participants was satisfactory. As many as 37%, and 21 % of total congress attendees participated in the events on the two days, respectively. It promoted discussion and opened up for questions especially from the young participants. Valuable conclusions for the further integration of the European research area for the pharmaceutical sciences were obtained.

All beginnings are difficult. In spite of a relatively low response for para-scientific events the interest was there. The sessions took place but under informal conditions and were lively. The concept needs refinement, and better and earlier announcement.

3.3 Forum events

The philosophy behind the forum events was the following: To stay on top in research and in business you have to focus and go straightforward to the goal. On the other hand the results of your research influence the society and accordingly the public world and through the politicians it again will influence the research through their regulations and laws. Since the numbers of conferences and congresses, the average scientists can attend, are limited, it was wanted to gather them in an "All-in-one congress". In this way it should be possible for the scientist with a minimum consumption of time to get informed and be involved.

However, the practical obstacles for the para-scientific forum events were too high to meet the ambition. Even though most of the planned events were there it has not been possible to attract the expected participants from big and small pharma industries in sufficient numbers. There are several reasons for that:

- Too few potential users were present. The invitation letters to companies, organizations (public and private), institutions etc. were not sent out early enough. Copies of the letters are found in Annex 5. Even though two mailing rounds were performed very few responded to the invitations. Industry participants represented about 50% of the total number of participants.
- Late announcement of the Afternoon Specials, due to late contract negotiations with the Commission.
- Competition from the Biotech meeting held in Medicon Biovalley, Lund two weeks before our event.

Outcome

The results of the planned events announced as "Meet the Specialist" can be summarized as follows.

Meet EU Directorate for research

The presence of Drs. A. Aguilar and T. Ingermansson from the EU directorate gave the necessary opportunities for contact not only at official presentations at the Afternoon Specials and the consortia event but also during the conference where they participated in the general discussion. It would of course have been an advantage if a booth had been open during the congress.

Meet the regulator

Professor B. Aronsson, EMEA, and Dr. G. Alvan, Swedish Medicine Agency, were present at the congress where they gave a plenary lecture and talked at the Afternoon Specials, respectively. A full session was devoted to the subject.

Meet the finance

No official event for presentation of projects and start-ups were arranged for. However, the finance people operated at the Congress but in a discrete manner. Professor C. Bogentoft, Karolinska Invest and Professor C. Post, Danske Life Science were announced. Furthermore, financing was discussed at the Biotech Innovation session.

Meet the big pharma
The congress had several presentations of big pharma: J. M. Lundberg, AstraZeneca, K. Müller, Roche, C. Richard Jones, Johnson and Johnson. No official job bourse was established due to lack of response from the invited companies, but intensive head hunting took place among the bright PhD students at the poster session. The organizers are aware of several Ph.D.-students were invited to come and present their results at the research headquarters.

Meet the ethicists
The Afternoon Specials on Ethical aspect had a very good discussion and the speakers from the session enjoyed walking around and talk to the scientists. Their experience is that nearly all scientists at the congress are faced with ethical issues, but that they seldom talk about it due to lack of qualified people to go into dialogue with. They express their willingness to participate in future conferences.

Meet the press
Two experienced journalists J. Degett, European Science Foundation (ESF), Strasburg, and B. Øksnebjerg, Novozymes, Copenhagen had a fruitful session regarding pharma/public interface: "Dialogue with the public". Here it was mostly the younger scientists that took the topic seriously. At this very useful course many "tricks" were given on how to avoid misunderstandings in communication.

Meet EU support organizations for SMEs
The topic was subject for T. Ingermansson's talk in the second session on EU 6th Framework programme, but no further service was afforded.

Meet your science organization
Besides EUFEPS International Pharmaceutical Excipient Council (IPEC), European Federation of Medicinal Chemistry (EFMC) and COST B15 and International Society of Xenobiotics (ISSX) took part in the organization of Congress, visibility were represented with tabletops. Furthermore an Afternoon Specials was devoted to European scientific associations.

Meet your local start-up company supporter
Surprisingly the congress could not attract representatives from the bioregions of Europe to present their activities. The reasons behind this need further exploration.
There was arranged for a speaker's corner with microphone and reservation list. No serious attempt to use it was conducted.

3.4 Call for consortia for FP6 application

Through the meeting "Call for consortia for FP6 applications", which took place in the lunch break on Tuesday, the aspect of formulation of networking and consortia building was promoted.

The aim of this event was to encourage, facilitate and establish contacts and interaction between scientists and other parties interested in or considering participating in and submitting an application for FP6. Professor O. J. Bjerrum, Copenhagen DK chaired the meeting and the Commission was represented by Drs. A.

Aguilar and T. Ingemansson. More than 40 persons participated and nearly all forwarded questions.

Without doubt the session raised the awareness of the conditions needed for networking and consortia building. The EUFEPS secretariat/chairman has during the month following the congress got enquiries regarding specific pharmaceutical networks and the role EUFEPS could play in this regard.

3.5 Exhibition

A small exhibition comprising 26 companies: CROs, suppliers of excipients, instrument makers, other service companies and publishers also took place. Most were satisfied with the integrated approach of the congressed and said that they intended to participate in future events.

3.6 Press and communication activities

The press release documents send out in connection with the Congress are attached as Annex 4. They concern European trends and news. The new safe medicines faster concept and a presentation of the Nobelprize winner Professor Arvid Carlssons new patent protected medicine against Parkinssons disease. The press conference gathered 6 journalists from Reuters, Swedish Radio, the newspaper "Dagens Nyheter and the margazines "Läkemedelsvärlden" and "Kemivärlden Biotech", who all wrote articles about the congress.

4 Conclusions and recommendations

The para-scientific events represented a valuable add-on to the classical programme of a congress. The topics chosen seem to have excited the interest of the scientific community. They are important for the modern scientist and are here to stay. Since pharma and biotech have so much in common the barrier between the two sectors should be broken down. The "All-in-one" concept for a congress is manageable. However, additional funding is needed until the concept is so well established that the increased attendance can pay for the extra sessions. Based on the experience from this congress integration with the ordinary programme is preferable.

From a practical point of view following points should be taken up early on:

- Know your target group.
- Addresses and contact details for potential non member delegates are difficult to obtain.
- Prepare promotion material early on.
- Announce in due time.
- Get deals in place with key players.
- Allow time and space for informal activities. It happens anyhow.

5 Appendices

1. **Final programme EUFEPS 2002 Congress**
2. **Abstract booklet**
3. **Afternoon Specials Programme**
4. **Press release**
5. **Invitation letters**

HYPERLINK

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