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EUFEPS Today

Background

EUFEPS was founded 17 years ago. Since then, its membership, activities, relations and collaborative operations have expanded a lot, even beyond European borders, as it has entered the global arena. The Swedish Pharmaceutical Society/Academy of Pharmaceutical Sciences (SAPS) provided substantial support during the first years, to run a professional secretariat. As this support came to an end, funding has been replaced by project grants from the European Commission, by income from congresses, conferences, workshops and courses, by more members, as well as by uncommitted support from a number of pharmaceutical companies.

Nearly ten years ago, EUFEPS started initiating and setting up the New Safe Medicines Faster Project (NSMF), obviously, the successful forerunner of the current Innovative Medicines Initiative (IMI Joint Undertaking). The IMI is funded and run in close collaboration by the European Commission (EC) and the European Association of Pharmaceutical Industries and Associations (EFPIA).

So, what is EUFEPS today, at the beginning of the post-IMI-launch era? At the EUFEPS President's Conference, in April this year, a set of slides were prepared for information and update. This rhapsodic article is based on them, together with some additional update material.

The Central Office of EUFEPS is still located in the SAPS building in Stockholm, Sweden. Since one year ago, there has also been the Branch Office Systems and Learning, at the University of Vienna, Austria. Additional Branch Offices have been considered, but these plans did not yet materialise.

Mission

What is the mission of EUFEPS? You know it, but why not refer to it as a reminder of the role of EUFEPS and



Hans H. Lindén
Executive Director EUFEPS

achievements anticipated. It reads (Strategic Plan 2006-2010):

The mission of the European Federation for Pharmaceutical Sciences (EUFEPS) is to serve and advance excellence in the pharmaceutical sciences and innovative drug research in Europe, including in training and education, and to represent the interests of scientists engaged in drug research and development, drug

regulation, drug utilisation, and drug policy making.

Implementation

Why invest time, energy and money in an organisation like EUFEPS? There was – and there is still – a job to be done, which cannot be delivered by any other current European organisation. For example,

- To underpin the only pan-European body for pharmaceutical scientists (whatever their origin, domain or discipline)
- To proactively support systems approaches in European collaboration, co-operation and co-ordination for better drug research, development and use
- To further strengthen the European voice and platform for needs and progress communication along with beneficial networking, including globally

Operational platforms

How to get the job done? The current structure, as it developed over the years, includes a number of “platforms of operation”, the ultimate responsibilities for which are shared by the Council, the Executive >>>

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Committee and the Secretariat. The Executive Committee, chaired by Daan J.A. Crommelin, present President of EUFEPS, includes the Executive Director (with voice but no vote). In addition, there are steering and other committees, many scientific programme committees and organising committees for meetings and events, plus ad hoc project groups and task forces, etc.

The platforms are, in summary:

- Membership Management
- Networks (covering certain specific fields)
- Senate
- Research and Policy Initiatives
- PharmSciFair
- Meetings and Events
- Education and Training
- Communications
- Finance and Funding
- President's Conference
- Council and Open Forum
- Central and Branch Offices

Membership

What constitutes the current membership of EUFEPS? It is:

Member Societies

- 24 in 24 European countries (including Israel and Turkey)

Member Institutions

- It's a new category, at present including 15 European universities and research institutions

Member Individuals

- Around 400, currently, including from non-European region; the number is a little lower than it has been for a number of years

There is a EUFEPS Steering Committee for Membership Development, chaired and co-chaired by Buket Aksu, Executive Committee Member, and Ole J. Bjerrum, Past-President of EUFEPS, respectively.

Networks

What are they and why? They are there to increase networking, of course, in and between scientific domains that are both relevant and important for drug discovery, development and use, initiated and run by scientists in the field. Current EUFEPS Networks include:

BioAvailability and BioPharmaceutics (BA/BP)

- Chaired by Henning Blume, Oberursel DE
Process Analytical Technology Sciences (PAT)

- Chaired by Peter York, Bradford UK
(retiring; new chair needed)

Pharmacogenetics and Pharmacogenomics Research (PGPG)

- Chaired by Anke-Hilse Maitland-van der Zee, Utrecht NL

Safety Sciences

- Chaired by Helmut Sterz, Paris FR
(retiring; new chair needed)

Additional Networks are emerging or being considered, including on "Environment and Pharmaceuticals" and on "Quality of Medicines", respectively.

For each EUFEPS Network, there is a Steering Committee, composed of members of the Network, as their time and availability allow, with support from the EUFEPS Executive Director and Secretariat.

Senate

What is this? It is a new EUFEPS-linked institution, formed as the outcome of discussions on how to aggregate scientific opinions relevant for drug discovery, development and use. The discussions started several years ago. Now, top scientists in Europe have been identified and listed, representing the full spectrum of scientific disciplines. A first round of personal invitations has been circulated, and most of those approached have responded positively. Additional invitation rounds will follow, to arrive at as complete as possible a coverage and representation of the pharmaceutical sciences in Europe.

Douwe D. Breimer, Founding Father and Past-President of EUFEPS, and Christian R. Noe, Past-President of EUFEPS, are in the lead.

Research and policy initiatives

Is this activity platform crucial to the further development of EUFEPS? Yes, it is. It is a conglomerate of EUFEPS activities and projects, many in collaboration with each other. It's all there to further regional and global development of the science and better serving the citizens. Significant "old", ongoing and new efforts include:

Projects in the European Arena

- Several projects funded by European Research Framework Programmes, over nearly 10 years

- Recent IMI JU Expressions of Interests, where EUFEPS is engaged in four out of five of the ones on education and training, one of which through the EUFEPS Network on Safety Sciences, particularly

- The European Bio(Tissue)Bank Project on Adverse Drug Reactions, initiated and run by the EUFEPS Research Network on Pharmacogenetics/Pharmacogenomics

Additional collaboration in the European region

- Good, high-level relations with other

(pan-)European institutions and agencies, including the EMEA, the EDQM (European Directorate for Quality of Medicines, the European Pharmacopoeia, primarily), ISPE Europe (International Society of Pharmaceutical Engineering), ESF (European Science Foundation) and more – all having instruments to be utilised for new research initiatives

-The European Pharma Sciences Leadership Forum (EuPSLF), comprising the Presidents of ten European sister federations/associations, in full operation representing the European scientific community devoted to contribute to new and better medicines

Bilateral collaboration

- Links forged with associations and agencies in the USA (including the FDA and USP), Japan and in the United Arab Emirates

Global collaboration

- The FIP Board of Pharmaceutical Sciences (BPS) is seen as the only current global platform. The presence of EUFEPS is now changing from observer to full member status

Industrial and academic research relations

Any other? As the NSMF has developed into the IMI JU, contacts with industry have been frequent, of course. However, there is an even longer industrial research relations initiative in EUFEPS, still ongoing.

It is the EUFEPS Committee on Industrial Research Relations (CIRR), established in the very first years of EUFEPS. Since 1994, it has been meeting regularly, mostly twice a year. As a very committed "think-tank" of EUFEPS, the CIRR contributed a lot to, for example, the meeting and course programme. Also, the first NSMF ideas emerged in a visionary and creative CIRR discussion.

Over the years the vast majority of delegates in EUFEPS meetings have been representing industry. This is not surprising, since industry research needs and progress, including in education and training, have been given a high priority.

For a relatively short period, there was also a EUFEPS Committee on Academic Research Relations (CARR), producing an important report on priority needs in the field. Chances to meet were few, though, because of limited funds among its membership. As establishing a EUFEPS Senate is now in progress, it is agreed that the tasks of CARR could be continued in this new group: the Senate.

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Awards

Since it is important to recognise excellent contributions to the development of the research field, EUFEPS has an award scheme. What are the EUFEPS awards? There is the (biennial) Segré Prize in Pharmacokinetics and Pharmacodynamics, the (annual) NSMF Award for new approaches, and the (annual) Best Paper Award for articles published in the European Journal of Pharmaceutical Sciences.

PharmSciFair

How does it go? The first Pharmaceutical Sciences Fair and Exhibition ever – PharmSciFair – was successfully held in June 2005 in Nice FR, and organised by 26 Programme Providing Partners, including EUFEPS. The initiative was taken several years before within EUFEPS. The idea was then that it should be the start of a joint European networking meetings platform, or the “European Congress Week”, where all relevant disciplines should come together and set up their “own” programme. By this, there would be a unique opportunity to learn about progress in one’s own and other disciplines. All this with the intent to stimulate data and information exchange, as well as many interactions.

Components of the PharmSciFair include:

- Opening Session
- Awards Ceremony
 - Including a prestigious European Pharmaceutical Sciences Award
- Invited Speaker Sessions
- Short Communication Sessions
- Discussion Sessions
- Poster Sessions
- Partner Introduction Stands
- Exhibition
- Welcome Reception
- Partner Receptions
- PharmSciFair Dinner

In 2007, there was no full PharmSciFair, because this was the year of the Pharmaceutical Sciences World Congress – PSWC2007 – in Europe. To link these events, there was the PSWC2007 and PharmSciFair Exhibition

The 2nd PharmSciFair is scheduled for June 8-12, 2009, again in Nice FR. Programming is in progress (7-8 parallel sessions for five days, except the first afternoon for the Opening Session), coordinated by a PharmSciFair Planning Team, chaired by Pia Vuorela, President-Elect of EUFEPS. The general concept will be the same as in 2005, but it will be expanded with a first European Careers Forum

and a

Young Scientists Meeting
- Pre-satellite with and for PhD Students and PostDocs

Meetings and events

What about them? EUFEPS’ conferences and workshops – 4 to 8 per year, normally – are widely communicated and well-known. They appear in three categories:

EUFEPS organised ones

- All responsibility, including risk and revenue

EUFEPS co-organised ones

- Shared responsibility, including risk and revenue

EUFEPS co-sponsored ones

- e.g. communication support, but neither risk nor any revenue

In addition, to education and training workshops, EUFEPS also set up a number of exploratory and discussion workshops, over the years, several funded by the European Commission. Important outcomes reports or articles have been published following such meetings. The number of delegates in such workshops ranged between 12 and 120. This activity should continue to ensure further contributions to the science and to policy making.

To run it all, there is an EUFEPS Steering Committee for Meetings and Events, chaired by Pia Vuorela, President-Elect of EUFEPS.

Education and training

How does EUFEPS engage in education and training? Courses, workshops and the Young Students Meeting (see above) are organised along similar lines as the meetings and events.

After many years of discussions, the EUFEPS Course DataBase or Catalogue was launched earlier this year. The information included in it is provided in collaboration with universities and research schools. A number of inclusion criteria have been defined to set the standard.

In-silico Systems and Learning is an additional new initiative. The initiative originates from Austria, where the University of Vienna is providing support for a EUFEPS Branch Office. One workshop has been held to engage more groups and expand collaboration. A second workshop is in progress.

EUFEPS organised two (exploratory) workshops in safety sciences. One of them a number of years ago (to feed into the NSMF) and an additional one, last year, to further address the needs of (integrated) research

education and training in safety sciences. The primary outcome was a tentative post-graduate level training programme for safety scientists in industry. In the first half of this year, it has been further developed and refined into a one-year modular curriculum, also submitted as an IMI JU EoI (Expression of Interest) by a specific consortium. There are additional ideas, along the same lines for additional topics, which will be reported on in due course.

Having assessed the needs and defined the goals and objectives, places where effective and efficient education and training (including lab courses, as needed) can take place are required. To start looking into how to assess the quality of institutions, a workshop on Institutional Peer Reviewing was set up in the beginning of this year. The workshop outcomes have been presented in a recent article in this NewsLetter.

Additional associations and groups for education and training liaising with EUFEPS include EAFP (European Association of Faculties of Pharmacy); EPSA (European Pharmaceutical Students’ Association); and the ULLA university consortium, running e.g. the ULLA Summer School.

For many years, the Committee on Training and Education (CTE) has been the EUFEPS group to identify, initiate and bring in courses to constitute the EUFEPS training and education programme. It is still there, but has, recently, been given a broader role – the EUFEPS Steering Committee for Education and Training, charged to coordinate all education activities. This Committee is chaired by Ulrike Holzgrabe, Member of the Executive Committee.

Communications

What are the EUFEPS communication tools and channels? In preparing the slide set, referred to in the beginning this article, a surprisingly long list emerged:

European Journal of Pharmaceutical Sciences (Eur J Pharm Sci or EJPS)

- Official Scientific Journal of EUFEPS; the Impact Factor of which is gradually increasing

EUFEPS NewsLetter

- Four issues per year, since a number of years no longer printed, but available at EUFEPS Online

EUFEPS Flash

- Email announcements of EUFEPS meetings and events, as needed

EUFEPS Membership Bulletin

- Email circulation to the membership

EUFEPS Online www.eufeps.org

- The EUFEPS central website

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EUFEPS Course DataBase/Catalogue

www.etplatform.eu

- *Linked to EUFEPS Online*

EUFEPS Vienna Branch Office

<http://vienna.eufeps.org>

- *systems and learning related website*

PharmSciFair Website

www.pharmscifair.org

- *The Pharmaceutical Sciences Fair and Exhibition partnership website*

- *Operated by EUFEPS*

EUMAPP Website www.eumapp.com

- *EU funded microdosing and accelerated mass spectrometry investigation project*

- *Operated by EUFEPS*

PSWC2007 Website www.pswc.org

- *The last Pharmaceutical Sciences World Congress website, still running*

- *Operated by EUFEPS*

Network on BioAvailability and

BioPharmaceutics www.babp-network.org

- *Linked to EUFEPS Online*

Network on PAT Sciences

- *On EUFEPS Online*

Network on Pharmacogenetics and

Pharmacogenomics Research

www.epr-network.org

- *Linked to EUFEPS Online*

Network on Safety Sciences

- *On EUFEPS Online*

European Pharma Sciences Leadership

Forum (EuPSLF) Website www.eupslf.org

- *Agreed to be set up*

EUFEPS Ambassadors

- *Members, meeting delegates and liaison*

contacts promoting EUFEPS and its activities

There is a EUFEPS Media Task Force, chaired by Hans H. Linden, Executive Director, available to discuss improvements and resolve problems.

Enabling things

What support is there? Any organisation is dependent on policy and decision-making bodies to succeed. As important are sound finances, hands to get the job done and facilities in and from which to operate. Such platforms include:

Finance and Funding

- *Membership dues*

- *Meetings registration fees*

- *General and specific sponsorship*

- *Budgets and outcomes reports*

President's Conference

- *Update, discussion and advice between*

council meetings

Council and Open Forum

- *The membership representatives legal meeting*

- *Strategic plans, progress and reports approval*

Secretariat and contracted partners

- *Central (executive) office and branch office*

- *General management and administration*

- *Project management and administration*

Where next?

Are there reasons to be satisfied? At the forthcoming Council and Open Forum (September 20, 2008, in Ljubljana, Slovenia), there will be a Mid-term Assessment of the current Strategic Plan (2006-2010), reflecting on what happened to date and discussing how to proceed. Outcomes will be reported in this NewsLetter.

Hans H. Linden

Executive Director EUFEPS



PhysChem and ADMET Profiling in Drug Research The 4th LogP Symposium

February 8 - 11, 2009 ETH Zürich, Switzerland

Day 1: PhysChem

(ionisation, solubility, partitioning, permeation - experimental and in silico)

Day 2: ADE

(transporters, absorption, distribution, excretion - in vitro and in silico)

Day 3: MeT

(metabolism and toxicity - in vitro and in silico)

info-LogP2009@pharma.ethz.ch

www.LogP2009.ethz.ch

early bird registration until October 31, 2008



Speaker Sessions • Posters • Careers Forum
Exhibition • Young Scientists Meeting

2nd

PHARMSCIFAIR

Premier European Platform for Advancing Pharmaceutical Sciences

2nd Pharmaceutical Sciences Fair & Exhibition & Careers Forum

June 8-12, 2009, Nice, France

Young Pharmaceutical Scientists Meeting as Pre-Satellite

June 7-8, 2009, Nice, France

The Pharmaceutical Sciences Fair & Exhibition (PharmSciFair) is a European platform, coordinated by EUFEPS, on which pharmaceutical sciences associations, organisations and societies set up their scientific programme sessions and information stands. These groups bring together their own and other people to contribute to enjoy the science – as well as utilising the exhibition, the careers forum, the social programme and the location. Components of the platform include:

- Attractive scientific programme, including speaker and poster sessions
- Vibrant exhibition and poster area, including association/organisation/society stands
- Careers Forum, matching recruitment needs to current competence
- Pre-Satellite Meeting by and for PhD Students and Postdoctoral Fellows
- Social Programme, including reception, dinner and events provided or “flagged” by the PharmSci Fair partners
- Excellent location

Scientific Programme Providing Partners

As for the 1st PharmSciFair, in 2005, there are many Programme Providing Partners. Partners, including associations, organisations and societies, are setting up, announcing and running one or more (half-day) programme sessions.

Scientific Programme

The PharmSciFair scientific programme is built around half-day sessions of 40-minute presentations by invited speakers and 20-minute shorter communications, invited or selected from abstracts submitted. There are also poster sessions based on the abstracts submitted. The programme includes broad themes of interest for pharmaceutical sciences and pharmacy. All abstracts will be peer-reviewed by poster committees for their possible acceptance. The committees will also categorise abstracts to structure the poster session in accordance with the scientific lecture programme. For speakers and their specific lecture titles, see the second announcement, which will be circulated and available on the PharmSciFair Website, at www.pharmscifair.org shortly.

Opening Session

The Opening Session, including the European Pharmaceutical Scientist Award Ceremony, is scheduled for the afternoon of the first day. (In the morning, there will be the Young Scientists Meeting as well as a number of parallel sessions on chosen topics, e.g. on alternative methods to animal tests in drug development) The Opening Session will focus on Individualised Medicines Therapy. High-level prominent speakers have been invited to give their views. The session will be followed by the Welcome Reception at the Nice Acropolis Terrace.

Exhibition and Partner Stands

Over 50 organisations showcased their products and services in a vibrant and stimulating exhibition at PharmSciFair 2005. Health Links will again be responsible for the exhibition. The exhibition at the 2nd PharmSciFair takes place over three days – on the Tuesday, Wednesday and Thursday – and will once again feature key players from the European Pharmaceutical Industry and beyond, as well as leading international companies from the supply chain. For more information on exhibition and exhibition sponsorship packages, please visit www.healthlinks-events.co.uk/pharmsci2009.htm

In addition, there will be PharmSciFair Programme Providing Partner Stands as well as EUFEPS Member Societies and Organisations providing information and hand-outs, in or near the Exhibition area.

Careers Forum

There will be a (European) Careers Forum at the 2nd PharmSciFair, provided by EUFEPS and Partners, in association with both AAPS (American Association of Pharmaceutical Scientists) and EPSA (European Pharmaceutical Students Association). It will provide an opportunity for companies, institutions and other organisations to meet with candidates, and to interview them for roles in their organisation. These opportunities will principally be of great interest to graduate students, and to those in the early stages of their professional careers in industry. It is anticipated that there will be opportunities available for other Life Science disciplines as well, including chemistry, biology, physics and informatics. For more information, see below.

Pre-satellite PhD and PostDoc Students Meeting

The Young Scientists meeting (see box), made up of a number of sessions, is a follow-up of the (new) series of PhD students and PostDoc meetings. The first one was held at the Pharmaceutical Sciences World Conference (PSWC) in April 2007 in Amsterdam NL. It will give young pharmaceutical scientists an excellent opportunity to network and share professional experiences before the start of the 2nd PharmSciFair, for which they are also invited to register and attend. Professor J. Siepmann, Lille, France, is chairing the Young Scientists Meeting.

For more information, see page 10.

Announcements and Information

All should help to circulate information and announcements about this event, including the pre-satellite meeting, not only the PharmSciFair Programme Providing Partners and/or EUFEPS Member Societies, Member Institutions and Individual Members. All should join as well, making it the European platform for scientific progress communication in all disciplines that are relevant for drug discovery, development and use, directly or indirectly.

Date and Location and Information

As indicated, the 2nd Pharmaceutical Sciences Fair & Exhibition & Careers Forum & Pre-Satellite will be held on June 8-12, 2009, in Nice, France – at the Nice Acropolis Congress Centre, which is the same as in 2005. It provides excellent surroundings with high quality meeting and exhibition facilities, located in the City Centre, within walking distance from many hotels and attractions.

For further information, access the PharmSciFair Website (www.pharmscifair.org) or contact any of the 2009 PharmSciFair Programme Providing Partners (see website), or the EUFEPS Secretariat (secretariat@eufeps.org), or Chris Hanney (channey@health-links.co.uk) for the Exhibition and the Careers Forum, or myself (pia.vuorela@abo.fi).

Hope to see you all at the 2nd Pharmaceutical Sciences Fair & Exhibition!

*Pia Vuorela, Abo Akademi University, Finland
Chair 2009 PharmSciFair and Planning Team*



Conference Report

When Variability Becomes an Issue in Drug Development: How to Understand, Predict and Manage?

May 13-14 • 2008 • Centro Congressi GSK • Verona • Italy

The individual human being remains a dynamic organism throughout life. Beside the one life cycle starting with birth and ending with death, a human has seasonal, monthly and daily cycles, and sometimes exceptional cycles caused by transitory diseases. Despite this fact, drugs are developed for large populations throughout the globe taking into account the individual's origin, genetic predisposition, life style, habits and compliance to a prescribed therapy. The objectives of the conference were to understand, predict and manage pharmacokinetic (PK) and pharmacodynamic (PD) variability within the new medicines development process, aiming at safe and effective drug treatments for patients.

Understanding variability

Oral drug absorption and its resulting bioavailability in the systemic circulation is a complex process which has been investigated thoroughly in recent years. The Biopharmaceutics Drug Classification (BCS) was introduced into drug development as a practical way to identify the compounds at risk for poor and variable oral bioavailability, based on their permeability and aqueous solubility. Poor bioavailability is not necessarily a problem per se as long as the drug is absorbed in a consistent manner leading to an effective and safe oral medicine. However, low bioavailability becomes an issue when high variability between patients and within the same patient compromises safety and efficacy.

Variability in pharmacokinetics and/or pharmacodynamics can be caused by drug substance factors and/or physiological differences as well as specifics of a patient population. In the case of drug substance related factors, it is well known that the physico-chemical properties of the drug substance like molecular weight, pKa, log P or polymorphic forms can impact the solubility and/or permeability. The impact can either be expressed in the form of a poor bioavailability or a variable bioavailability in the presence of food. If the drug compound is a substrate for metabolic enzymes like the cytochromes CYP 2D6 or CYP 2C9, the genetics of individual patient will determine the achievable plasma level. While ultra-rapid metabolizers do not achieve the effective >>>

plasma concentration, poor metabolizers will have high plasma levels, that may lead to serious side effects. Beside the genetic predisposition of the individual, a variety of other factors have a direct impact on the PK/PD profile of a given compound. Age, gender, sex, weight, race can be determine drug absorption and distribution. Organ size or functions like hepatic and renal clearance, blood flow parameters, plasma protein concentrations and haematocrit can lead to variable plasma concentrations of the drug and/or metabolite. A low plasma albumin level can increase the free drug in the blood leading the undesired side effects at the same total plasma concentration as in another patient. The disease itself or concomitant disease conditions can modify the absorption, distribution, metabolism and elimination of a compound. Time of day, compliance, fed or fasted state, other drug treatments, smoking and alcohol intake contribute to pharmacokinetic and pharmacodynamic variability as well. Recently, constant monitoring studies of orally delivered dosage forms have been developed to investigate the true gastric transfer. These studies suggest that gastric transfer is not a sequential process. In contrast, the dosage forms move several times, unpredictably in both directions. Such movements will contribute to variability, as well as the fluid distribution in the GI tract, which varies between the subjects.

Clinical

Variability, from a clinician's point of view, is classified in interindividual (between-subject) variability, interoccasion (between-occasion) variability and residual (unexplained) variability. To distinguish between these sources of variability, studies evaluate several individuals at different occasions and with at least 2 different observations per occasion. Variability is still mainly measured as PK variability. However, many efforts have been put into the identification of biomarkers to measure the true PD effect of a drug *in vivo*.

Investigating variability

Investigations into potential variability are done early on in development, using tools like *in silico* GastroPlus™ or Simcyp™ simulation models, the *in-vitro* TNO™ Intestinal Model, and magnetic resonance imaging for orally delivered drugs. In conjunction with these tools, special capsules (Intellisite™ or 3D SPECT cameras) have been developed for better understanding of the absorption patterns in certain areas of the GI tract. In conjunction with the preclinical data on drug metabolism, studies to investigate potential



patients at risk (e.g. renally impaired) or drug-drug interaction studies are integrated into the phase II clinical program. These data are important for the clinical trial design for the phase III trials throughout which variability is continuously monitored.

The measures that are taken to manage the PK variability are dose adjustments, route of administration, crystal engineering, formulation design, exclusion criteria for patients at risk, or even discontinuation of a development program.

For orally administered products with poor solubility (BCS class II) crystal form, particle size and formulation are important factors to reduce variability. Formation of polymorphs, salts, co-crystals, hydrates and amorphous as well as particle size reduction can improve the aqueous solubility in the GI tract. Formulation approaches like self-emulsifying drug delivery systems, nanosuspensions or solid dispersions have often been used successfully in managing the PK variability.

Variability

Managing variability by exclusion of certain patient population requires validated and practical test methods for physicians in hospitals as well as outside hospitals. Genetic testing has already been established for some life threatening diseases (e.g. trastuzumab (Herceptin™), imatinib (Glivec™), erlotinib (Tarceva™). However, genetic tests for the poor or ultrarapid metabolizers are still in their infancy and have just been introduced for warfarin to reduce serious side effects due

to overdosing of a poor metabolizer lacking CYP2C9 and VKORC1.

Molecular biology has helped in the past decade to understand the complexity of diseases. The drug discovery and development process, especially for life-threatening diseases and for highly specific monoclonal antibodies, is more and more targeted towards complex disease targets. This process runs in conjunction with relevant diagnostics not only to identify the responding patient population but also to monitor the progress of the treatment.

Managing variability is a task common to the pharmaceutical industry, regulators, the physicians, the health insurance system, pharmacists and the patients. Today, variability is addressed by pharmaceutical industry in the product development and reviewed by regulators. Despite some known genetically dependent diseases, physicians still lack validated diagnostic tools and guidance on their application for individualized therapy. Once physicians are trained how to individualize dosing, in order to reduce the PK variability and determine responders through genetic testing or use of biomarkers, health insurance companies will have to pay and pharmacists will have to be trained to guide the patients through their therapy.

Sven Stegemann, Pfizer
Workshop Co Chair

Report of EUFEPS and DPhG Workshop

Development of Safe Protein Therapeutics: Preclinical, Clinical and Regulatory Issues

On March 10th and 11th 2008, a workshop on the development of safe protein therapeutics was organized by EUFEPS together with the Deutsche Pharmazeutische Gesellschaft (DPhG). It was held in Munich and attended by 120 participants including many industrial and regulatory scientists.

The idea for a workshop specifically focused on issues related to protein therapeutics came up during the EUFEPS workshop on safety sciences, organized in Vienna during June 2007.

The reasons to run this event can be found in the programme announcement.

‘Today, a major fraction of NDAs concerns pharmaceutical proteins produced by recombinant or hybridoma technologies. These large molecules differ from low-molecular-weight drugs because of their complex, rather unstable structure. In addition, they are often (derived from) endogenous proteins and species-specific in their actions. These characteristics lead to approaches for the development of these protein-based medicines that are different from low molecular weight drugs. Therefore, the objectives of this workshop include:

- To present the state of the art of the in vitro and in vivo assays and analytical tools to predict and assess the safety and efficacy of therapeutic proteins
- To discuss how to optimise production, purification and formulation of therapeutic proteins to reduce adverse effects
- To give an overview of relevant regulatory requirements and those under consideration for therapeutic proteins’

In five plenary sessions, expert speakers discussed different elements of safety testing of biopharmaceuticals

- Efficacy and safety testing
- Predicting immunogenicity
- Clinical experience
- Structure, quality and formulation
- Regulatory issues

In addition, specific questions were addressed during 6 breakout sessions.

In her opening address, Eva Muchitsch (Baxter) gave her view on the specific issues related to safety testing of biologicals when compared to testing of small, low molecular weight molecules. Several of the issues mentioned in

her presentation were considered in greater detail during Session I on Efficacy and Safety Testing by Christoph Ladel (Merck Serono), Huub Schellekens (Utrecht University), Beatriz Silva-Lima (University of Lisbon) and Martin Wolfsegger (Baxter). Because biopharmaceuticals require a special testing regime in their development, attention should be paid to avoiding irrelevant animal studies. For example, biopharmaceuticals often are species-specific and therefore testing in genetically modified animals, use of homologous proteins in vitro test systems should be considered. At present, a case-by-case approach is the most logical one to follow. Early interactions between industrial and regulatory scientists regarding the dossier contents are advised.

The next session was on approaches to predict immunogenicity. Birgit Reipert (Baxter), presented experience with genetically modified mice for the prediction of the immunogenicity of Factor VIII. Combined in vitro and in silico approaches to predict immunogenicity were presented by Philippe Stas (AlgoNomics). He illustrated the power of this approach with four case studies on new therapeutic proteins.

Clinical experience with pharmaceutical proteins was considered in three lectures. In the first one on preclinical and clinical biomarkers for predicting toxicity and therapeutic response, given by Mauro D’Antonio (Merck Serono), the biomarker concept and operational techniques were discussed. Jacques-Georges Descotes (Centre de Pharmacovigilance) described immunotoxic effects related to the use of biopharmaceuticals. Immunotoxic effects can be categorized in four types taking into account the clinical features of immunologic adverse effects and the specificities of non-clinical / clinical evaluation strategies: immunosuppression, immunostimulation / immunoactivation, hypersensitivity and autoimmunity. Dr. Descotes concluded that clinical immunotoxicity studies should be an integral part of the evaluation process of biopharmaceuticals. Finally, Alexander Berghout (Sandoz Biopharmaceuticals) outlined post-approval studies with biosimilars and in particular the design of post-marketing risk management plans.

Structure, quality and formulation, and their

relationships with the therapeutic performance of biopharmaceuticals, were the topics for three speakers. Patrick van Berkel (GenMab) talked about the impact of glycosylation of antibody therapeutics (e.g. IgG1). The importance of the glycosylation pattern for the potency of zanolimumab and the development of assays to monitor potency of this molecule in batch production were discussed. Aggregates can induce immune reactions causing loss of activity or immunotoxic reactions. Wim Jiskoot (LACDR) discussed clinical evidence and mechanisms behind aggregate-induced immunogenicity and the analytical toolbox to monitor aggregate formation. The last speaker in this session, David Zang (Barofold) showed examples of refolding and de-aggregation by applying high pressure to protein-containing formulations.

Last, but definitely not least, came presentations about regulatory issues by Jan Mueller-Berghaus (Paul-Ehrlich Institute) and Jan Willem van der Laan (RIVM). Mueller-Berghaus discussed the ‘CHMP Guideline on Immunogenicity Assessment of Biotechnology-derived Therapeutic Proteins’ and van der Laan addressed the question: ‘The ICH S6 Guideline. Is there a need for revision?’ Considering progress in the biotech field and new families of therapeutic compounds advancing to clinical test stages, it is clear that an update is desirable.

In the final wrap up sessions the conference co-chairs, Eva Muchitsch and Daan Crommelin drew their conclusions. But, more important than their conclusions was the outcome of the evaluation: 90% of the participants who returned the questionnaire answered the following question: ‘Taking into account the venue and the quality of speakers, did the Workshop represent good value for money?’ with ‘Yes’

And now what...? Further research on immunogenicity of biopharmaceuticals is foreseen in the framework of IMI (Innovative Medicines Initiative), a Public Private Partnership, in which the EU and the EFPIA (European Federation of Pharmaceutical Industries and Associations) will work together on understanding the basis of and prevention of immunogenicity (topic #1 of the first call).

Daan JA Crommelin, President of EUFEPS and co-chair of the Workshop

Positive Validation of the Microdosing Concept

Report of the EUMAPP Workshop on Microdosing in Drug Development: Current Status and Future Perspectives

The workshop was held at Maritim Kurhaus Hotel, Bad Homburg, Germany on June 16, 2008.

The workshop represented the outcome deliverable of the EU-supported project EUMAPP - the European Union Microdose AMS Partnership Programme - in which EUFEPS is a partner.

In fact it was the third workshop of the EUMAPP consortium. The first workshop dealt with microdosing *pros* and *cons* in translational medicine, as well as the objectives, strategy and expectations of EUMAPP. The second EUMAPP workshop presented the first preliminary results, safety issues in microdosing and the need for harmonisation between regulatory authorities. The present workshop concludes the scientific work.

The microdose concept

Microdosing is a new safe method from which information about the human metabolism and pharmacokinetics of a drug is obtained with minimal animal testing. In microdose studies, trace amounts of candidate substances for new medicines are administered to healthy volunteers and followed in the body. A microdose is less than 1/100th of the dose required to yield an effect of the test substance. The maximum dose is limited to 100 micrograms. Microdose studies can be completed in four to six months. This is significantly shorter than for any other comparable research methods.

Scope and aim

Microdosing is becoming more common in drug development, and there exists substantial evidence that this methodology is predictive in many cases. However, when can we say that the microdosing-approach is fully verified, and that its place in drug development is well defined? In the Workshop, outcomes of the EUMAPP project were presented and put into a wider context, placing microdose predictions beside those of the classical approach.

Participation and organisation

The workshop was busy and intensive with 56 registered participants from countries in Europe, plus a few from US and Japan.

The workshop chair was Professor O.

J. Bjerrum, University of Copenhagen with Drs. Graham Lappin, Xceleron, and Roeline Jochemsen, Institut de Recherche International, Servier as co-chairs. All three opened and introduced the workshop. Then followed a series of lectures about the EUMAPP microdosing results, in the order they would have appeared during the drug development process. This order gave rise to separate presentations by the same lecturer but it maintained a logical flow. A panel discussion with questions from the audience concluded the workshop.

Workshop session

Simon Thomas, Cyprotex, and Roeline Jochemsen alternated their presentations on classical pharmacokinetic predictions, based on *in vitro* and preclinical data, with those based on the new microdose data from the EUMAPP project.

The seven compounds, expected to have problems of predicting clinical pharmacokinetic behaviour from early data, were examined in a microdose study.

For the two compounds interacting with P-glycoprotein (Pgp), fexofenadine and clarithromycin, pharmacokinetics (PK) was well predicted, using the predefined criterion of good prediction being within a factor 2. Physiologically-based pharmacokinetics (PBPK) and microdosing gave similar results. Propafenone, with non-linear first pass extraction, was also well predicted. PBPK and microdosing gave similar parameters except that the microdosing under-estimated the bioavailability. Phenobarbital represented a very stable compound both *in vitro* and *in vivo*. Here microdosing predicted better than the PBPK studies. Three further compounds with non-CYP 450 metabolism, paracetamol, sumatriptan and S-19812 (a Servier compound) were tested. Microdosing predicted PK well for all compounds, albeit the clearance for S-19812 was low.

Brian Houston, University of Manchester combined the obtained results with data in the scientific literature for IV and oral microdosing. The IV route gave relative minor differences in PK. Oral comparisons were more complex as it seems that the Pgp capacity and first pass metabolism were saturated at pharmacological doses for clarithromycin and propafenone, respectively,

whereas paracetamol and phenobarbital showed good concordance.

Thus the EUMAPP microdosing study increases confidence of the predictability of microdosing as compounds thought to give problems were satisfactorily classified.

After lunch, Graham Lappin talked about "Analytical demands and tools to perform microdosing studies; first and second generation AMS and LC-MS" where he emphasized the need for new, sensitive and cheaper analytical techniques to allow a more widespread use of microdosing.

"The regulatory and ethical requirements and issues" were considered by Rokus de Zeeuw, BEBO. Although microdosing has been introduced while the ICH harmonisation process was in full swing, FDA and EMEA guidelines still show differences.

Malcolm Rowland, University of Manchester, talked about the "Contribution to and the role of microdosing and the EUMAPP project in the wider perspective: Lessons learnt". Here he foresaw a more widespread use of microdosing in the future, on basis of the presented results.

Due to late appearance of the experimental data, all the presented material had not been discussed in plenum between the EUMAPP partners beforehand. This gave rise to a freshness in the presentations, but also to concerns about the preliminary nature of the derived conclusions. For this reason, copies of the conclusive slides will first be released when the analyses have been confirmed by all partners.

Panel Discussion

There were lively discussions triggered by one hour's questions exclusively from the audience. The questions and answers are summarised below;

Regulatory aspects. It was concluded that there is a strong need for harmonisation of regulatory guidelines in connection with microdosing. Guidelines describe how one dose is given but can multicomponent mixtures be given i.e. cassette dosing? This was considered possible if the analytical challenges of detection/separation can be solved to the satisfaction of the regulatory authorities. Regarding human volunteers used for the microdose study, the question was raised how to test cytotoxic oncology >>>

compounds used for cancer treatment. Should only cancer patients be tested? Since no experience exists so far, this remains an open question.

Biologics. Guidelines describe administration of new chemical entities at 100 microgram doses. But what approach can be advised for biologicals where activity can be markedly different across species? Very little experience with proteins exists so far. In the UK, microdosing for biologicals is not recommended, since it does not fit into the national regulatory guidance.

Predictability. It was concluded as criterion for success that the results obtained by microdosing and by existing methods for pharmacological doses should be similar and within a factor 2, before the microdosing test was considered predictive. Using this criteria PK was well predicted.

Administration. Besides the oral route can microdosing be used for other Phase 0 studies? Microdosing can be used for different routes of administration. It has been applied for (trans)dermal application, and for I.V. administration of prodrug to see whether the active drug becomes available. Can microdose be used with sustained release? Most experience comes from dosing in solution like the EUMAPP study. However microdose studies may help to decide whether sustained release formulation is feasible, i.e. whether a drug can be absorbed in the colon.

The microdose should then be released in the colon, e.g. from specific formulations.

Analytical sensitivity and instrumentation. To allow a more widespread use of microdosing, a need for new sensitive and cheaper analytical techniques exists. Currently LC-MS/MS is not sensitive enough, but the technique has potential. Support should be given to develop new sensitive techniques. Accelerator mass spectrometry (AMS) methodology will improve when the demand increases.

Number of animals used in drug development. The widespread use of microdosing could reduce the use of animals, mostly by stopping development of a given compound before reaching phase 1, on the basis of results obtained from microdosing. However, microdosing will never entirely replace the use of animals in non-clinical development.

Attraction of investors. Microdosing increases possibilities for small biopharmaceutical companies (SMEs) to create human data on their proprietary drug candidates early on. What next for microdosing and AMS? Since the CREAM and EUMAPP projects have generated enough data to support the potential value, the companies will now have to decide whether and how they want to apply microdosing in their drug development strategy.

Conclusions

This was a real workshop, in the most positive sense of the word, with lots of interaction and enthusiasm. The workshop increased the comprehension of using microdosing as tool in the drug development process. It gave a clearer view on how to implement microdosing in the process. Many academic questions remain, but much has already been learnt.

AMS is very labour intensive, so progress needs to be made towards improved analytical methodologies. There is a need for new, sensitive, cheaper analytical techniques to allow a more widespread use of microdosing and a need for further development of modelling and simulation in connection with microdosing.

Ole J. Bjerrum
Past President EUFEPS
Workshop Co Chair

Pre-Satellite Meeting of the Pharmaceutical Sciences Fair & Exhibition for and by Ph.D. students and postdoctoral fellows

June 7 and 8, 2009, Nice, France

Continuing the concept of the very successful pre-satellite meeting of the Pharmaceutical Sciences World Congress 2007 in Amsterdam, the PharmSciFair 2009 is pleased to offer a pre-satellite symposium dedicated to the next generation of pharmaceutical scientists. PhD students and postdoctorate fellows from all over the world will convene in Nice to exchange ideas and discuss the latest developments in pharmaceutical sciences. During the one and a half day event, keynote

lecturers in all areas will give comprehensive overviews on the current developments in their particular fields and young scientists will present lectures in parallel sessions covering all aspects of pharmaceutical sciences. In addition, poster presentations will be held on the latest research findings in all fields of pharmaceutical sciences. The students/postdoctoral fellows will have the opportunity to present their work during "poster walks". In each scientific section, the

most outstanding poster presentation will be honored with a "Young Investigator Award".

Further Information

Please see:

www.apgi.org/presatellitePharmSciFair
or contact:

Mrs. Catharina Kroling, APGI, 5 Rue Jean Baptiste Clément, 92296 Châtenay-Malabry, France, Tel: +33-1-46 60 25 10, Fax: +33-1-46 83 53 08, Email: apgi.asso@u-psud.fr

Conference Report

EUFEPS Network on New Regulations in Bioequivalence: Revised European CHMP Note for Guidance

Discussion Forum

The primary intention of this EUFEPS conference was to provide a discussion forum for scientists and professionals from academia, generic and research based industry and regulatory authorities to contribute to the revision process of the European bioequivalence guideline (1401/98). Speakers from academia, industry and regulatory gave presentations based on latest findings to stimulate the discussion with all participants.

Information on speakers and their particular topics and presentations is available through the web-link: <http://www.eufeps.org/summer08061718.html>. The outcome of the sessions is briefly described as follows.

In Vitro dissolution

As a first topic, the experimental setting of in vitro dissolution testing as related to BCS-based biowaiver was discussed. It has been emphasized that the comparative dissolution between a test and a reference is the focus rather than product quality testing. Accordingly there was a strong tendency to consider gastro-intestinal conditions in-vivo in defining conservative experimental in-vitro conditions, e.g. less than 900 ml dissolution medium (with respect to available fluid volume in-vivo) and less than 30 min of sampling time (with respect to gastric emptying time of approx. 15 min). However, the comparative dissolution test should allow detection of possible formulation-related differences rather than the solubility of the active compound. Other tests, than f_2 , may be used to compare dissolution profiles, e.g. a calculation of mean dissolution time (MDT).

Excipients

Regarding the relevance of excipients in the framework of a BCS-based biowaiver, it was obvious that quality as well as quantity should be evaluated. However, the quantities are generally not publicly available from the originator product. Respective assessments may be difficult since little is known about specific effects of certain excipients on bioavailability of a particular active compound. Hence, differences in composition should be as small as possible

between test and reference products if a BCS-based biowaiver is attempted. Furthermore, it seems that dosage form, size, and shape are possibly of little relevance for a BCS-based biowaiver.

Forms, salts and profiles

From another presentation, it was concluded that BCS-based biowaivers may be acceptable for different polymorphic forms and different salts, if the compounds are highly soluble and safety is of no concern. However, current experience is limited to BCS-class I drugs only.

In case of drug substances with non-linear pharmacokinetics, the comparison of metabolic profiles is recommended according to a further presentation. In addition, thorough dissolution testing is necessary since even small differences in in-vitro dissolution may impact pharmacokinetic characteristics.

BCS class II and III

Further presentations tackled the question of biowaiver extensions to BCS class II and/or class III compounds. BCS-class II acids, having high solubility (according to the BCS concept) at intestinal pH and formulated for immediate release, may have a minimal risk for differences in extent of absorption from rapidly dissolving products. Differences in rate of absorption are more likely to occur which hints at the limited predictive power of respective in-vitro dissolution experiments. Extension of biowaiver to BCS-class III drugs seems to be obvious but may not be simple, considering possible effects of excipients on absorption processes of such compounds. The same very rapid in-vitro dissolution of 90 % within 15 min to be achieved with test and reference may exclude relevant formulation effects on drug substance bioavailability.

At the time being, it seems to be impossible to get specific information regarding the eligibility for BCS-based biowaivers from animal data.

Dosage forms

Another topic focussed on specific dosage forms like orodispersible formulations (ODTs) which are not addressed in the present guideline. It has been concluded

that, in principle, biowaivers may be possible for ODTs. However, there is currently no standardized experimental setting available for comparative in-vitro dissolution testing, making BCS-based biowaivers impossible for such formulations. Accordingly, appropriate designs for in-vivo bioequivalence testing were discussed regarding e.g. intake of water and/or food. The necessity of testing ODTs in the most sensitive and relevant setting i.e. without fluid intake has been emphasized.

Finally, the relevance and necessity of bioequivalence testing under steady-state conditions (i.e. multiple-dose studies) was the subject of some controversy. It seems agreed that multiple-dose studies are not justified for reasons of bioanalysis or high variability. In contrast, the general request for steady-state studies is justified for modified release formulations. At the time being, there is no final conclusion on what requests are scientifically sound for compounds showing non-linear pharmacokinetics. Accordingly, dose-dependent auto-inhibition of metabolism, drugs with saturated metabolism at steady-state and those with dose-dependent pharmacokinetics and low clearance may need further research and discussion.

Draft Bioequivalence guidelines

Thanks to the excellent presentations the discussions have been lively and fruitful and relevant points were well taken by participating regulators from different European member states. Meanwhile the draft revision of the bioequivalence guideline has been released by the CHMP for consultation (<http://www.emea.europa.eu/hums/human/humanguidelines/efficacy.htm>), including not only the topics addressed at the conference but more issues to be discussed during the upcoming months.

*Henrike Potthast, BfArM
Workshop Co Chair*

Disclaimer: The manuscript represents the personal opinion of the author and does not necessarily represent the views or policies of the German Federal Institute for Drugs and Medical Devices (BfArM).

The Innovative Medicines Initiative (IMI) continues into the next Phase

Numerous Expressions of Interest by Applicant Consortia make the first stage of the IMI Joint Undertaking's Call for proposals a success

From 30 April until 15 July 2008 Consortia of academia, patient groups, SMEs, regulatory organisations and non EFPIA industries have submitted their Expressions of Interest to the IMI Joint Undertaking (IMI JU) in answer to the first Call for proposals.

A total of 18 topics were addressed in this first IMI JU Call for proposals: 6 in the

pillar "Improving the Predictivity of Safety Evaluation", 7 in the pillar "Improving the Predictivity of Efficacy Evaluation" and 5 in the pillar "Closing the gap in Education and Training".

Close to 150 Expressions of Interest have been received, covering all topics opened in the Call.

Peer review committees will now evaluate the scientific excellence of the Expressions of Interest.

Following completion of the first stage peer review at the end of September 2008, the

best proposals from Applicant Consortia will be invited to join EFPIA industry members to form a "Project Consortium" which will develop the full project proposal. These proposals shall be sent to the IMI JU for the second stage peer-evaluation towards the end of November 2008.

Full project proposals favourably reviewed at the second stage evaluation can be selected for funding.

Contract negotiations followed by a kick off of the research activities are foreseen for early 2009.

Warning of Spam Message sent to Pharmaceutical Scientists

Below we reproduce the text of a message wrongly giving the impression as coming from Elsevier, the scientific publisher. This is a widespread and very annoying spam message, causing Elsevier considerable trouble and (as they know) filching quite some money from credulous authors. It is difficult to weed out.

Elsevier has nothing to do with these (and similar) emails and Elsevier does not issue such general calls for manuscripts.

It suggested that you do not respond to these emails, and that you forward the mail to emailabuse@elsevier.com for further investigation.

See the following link: <http://www.elsevier.com/wps/find/authorsview.authors/spam>.

-----Original Message-----

From: Elsevier Journals [Ed.: not from elsevier.com]

Sent: den 1 september 2008 04:46

Subject: Submission of Manuscripts!

ELSEVIER:

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On behalf of all the Editors-in-chief of Elsevier Journals, we wish to Communicate to you that we are currently accepting manuscripts in all Fields of human Endeavour.

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The submitted papers must be written in English and describe original research not published nor currently under review by other journals.

Parallel submissions will not be accepted. Our goal is to inform authors about their paper(s) within one week of receipt.

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*Kind Regards,
Rex Hammond(Prof.)*

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PSWC2010

In two years, there will be the next Pharmaceutical Sciences World Congress, on November 14-18, 2010, in New Orleans, Louisiana – organised by FIP in association with the AAPS Annual Meeting and Exposition and co-sponsored by additional American and European and Asian organisations. The overall theme is: Improving Global Health through Advances in Pharmaceutical Sciences.

www.pswc2010.org

EUFEPS Course Catalogue – online

Second announcement and invitation for comments and expansion

Rapidly changing demands, created by emerging science and techniques in pharmaceutical research and development, call for top quality education and training.

To facilitate post-graduate researchers (PhD students, Post-docs and research professionals, see figure 1, in fulfilling their training needs, a course catalogue is currently being built, providing an overview of high quality training courses in (bio-) pharmaceutical sciences and related subjects throughout Europe.

At the moment more than 400 courses from various universities in Denmark, Finland, Sweden, the Netherlands and Switzerland are included in the course catalogue which can be accessed via www.etplatform.eu.

These courses are in four main categories (Therapeutic Areas, Enabling Technologies, Methodology, and Auxiliary Skills) which are each divided into several sub-categories. Next to a search function, a filter option allows you to rapidly find courses of interest. The filter option includes cities and target groups. Figure 2 shows a screenshot of the website.

The EUFEPS Course Catalogue is currently expanding the database with courses from universities in other European countries. In the near future, the possibility will be opened to submit your own courses to the catalogue. At present, we focus on including complete sets of offerings per university. The website back office has a built-in updating system which checks every six months with the course organizers if the information is still up to date.

In the near future, the course catalogue website will also be expanded by introducing Master of Advanced Studies Programmes,

each of which consists of a defined mandatory number of individual Course Modules.

We have chosen to put this version online and we welcome suggestions from users,

please email us at info@etplatform.eu.

*Dr. Jorg Janssen
Top Institute Pharma, NL*

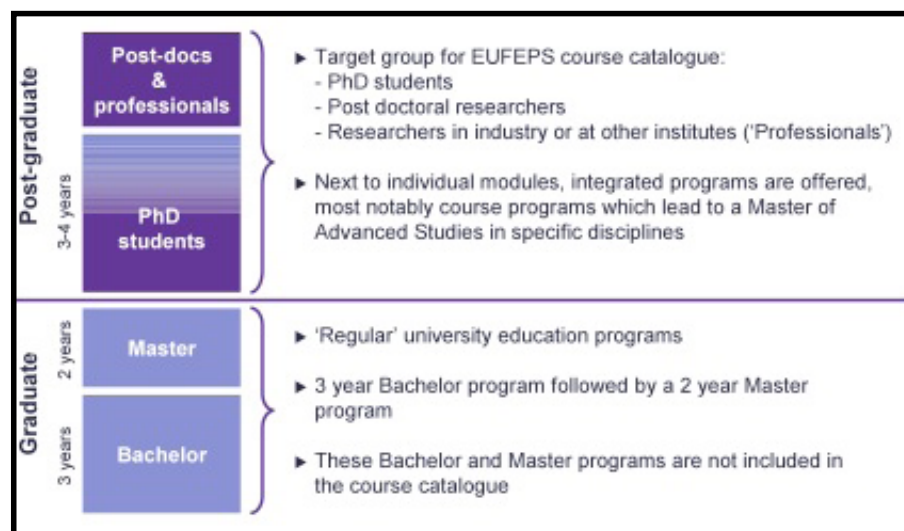


Figure 1: Target group for the course catalogue are post-graduates



Figure 2: Screenshot of the website: www.etplatform.eu

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European Research Network on Pharmacogenetics/Pharmacogenomics

In the end of 2005 in cooperation with EUFEPS the idea of organising a course on Pharmacogenetics/genomics in Europe was launched. Key people within the field were gathered and concluded that what was really needed in Europe was a Pharmacogenetics/genomics Research Network. A Task-Force Pharmacogenetics Europe was established. In November 2006 this Task-Force organised a 'Workshop on pharmacogenetics/pharmacogenomics, including Relevance for Personalised Medicines' in Utrecht, The Netherlands where European group leaders in the field of Pharmacogenetics/genomics were invited. The aim was to bring European scientists working in the field of pharmacogenetics together in order to develop a European roadmap for improving collaboration and research on pharmacogenetics in Europe. It was organised by EUFEPS and co-sponsored by the Utrecht University and by the FIP Board of Pharmaceutical Sciences. The newly formed Dutch Top Institute Pharma provided financial sponsorship.

A report of this meeting was published in the Eur J Pharmaceut Sci (2007;31:151-5). The outcomes of the meeting resulted in the establishment of the Pharmacogenetics/genomics Research Network Europe (www.epr-network.org). The objectives of this network are the following:

- To provide a platform for gathering and promoting knowledge about pharmacogenetics in Europe.
- To provide a mechanism for sharing and extending existing research, databases and bio-banks within and outside Europe.
- To encourage and facilitate input from and collaboration with the pharmaceutical industry both within and outside Europe.
- To improve education and training in pharmacogenetics/genomics.

At this moment more than 60 researchers have registered as participants of the network on the website. The Steering committee of the network consists of Anke-Hilse Maitland-van der Zee (chair), Ann Daly, Munir Pirmohamed, Hans Linden, John Caldwell, Jose Lanao, Ron van Schaik, Julia Kirchheiner, and Ingolf Cascorbi. The network also has an advisory board that is chaired by Michel Eichelbaum.

One of the first results of successful cooperation within the Network was the submittal of a European 7th Framework Programme Health grant. Contract negotiations with EU are nearly finalised with the aim to start this large pan-European trial by October 2008. Furthermore the steering committee is looking into the possibility of setting up a large European Adverse Drug Reactions Biobank together with pharmaceutical companies. By doing

this the network is providing the opportunity for European researchers to find collaborators within the field of pharmacogenetics. Other initiatives have started, and more projects are expected in the (near) future.

The network will organise a meeting on this Adverse Drug Reactions Biobank in February next year. Furthermore the network will organize two sessions at the Pharmaceutical Sciences Fair in Nice 2009. The subjects of these sessions will be "Pharmacogenetics of adverse drug reactions" and "Clinical Implementation of Pharmacogenetics".

The network provides an inventory of courses and conferences on the topic, advertised on the website. The website also provides the opportunity for members of the network to advertise vacancies within their departments.

Until now the introduction of the network has been very successful. Unfortunately until now no funding has been found to provide support for the network itself. Two COST proposals have not been granted... Hopefully the network will find funding because the future of pharmacogenetics/genomics research in Europe will be much brighter with the presence of a funded European Network.

*Anke-Hilse Maitland-van der Zee
Utrecht University, The Netherlands*

Establishment of First FIP Collaborating Centre

International Pharmaceutical Federation



4 June 2008, London

The International Pharmaceutical Federation (FIP) and the School of Pharmacy, University of London is pleased to announce the establishment of the first FIP Collaborating Centre (FIPCC). The purpose of the FIPCC for Pharmacy and Health is to serve as a conduit for expertise, research, capacity building, innovation and development in collaboration with key stakeholders including FIP Member Organisations, WHO and UNESCO. The FIPCC will provide expert institutional support through research, policy analysis and technical advice to enable and catalyse FIP's expanding global activity in medicines and public health policy, human resources for health and education. This

paper on Pharmacy and the prevention and treatment of Tuberculosis is the first of a series of papers from the FIPCC.

The FIP Collaborating Centre will aim to build the competence and capacity of individuals, institutions and countries to advance developments through projects, advice, and training. In summary, the key roles of the FIP Collaborating Centre are to:

- serve as a focus of excellence,
- gather expertise,
- provide capacity for projects,
- gather and build competence and capacity for development, and
- strengthen collaboration with the UN and other global agencies.

This FIPCC will be piloted over a three year

period. During this period it is expected that it will develop project plans in defined areas of work, develop its own infrastructure to operationalise the project plans, seek funding and strategic partners, develop a website linked to the School of Pharmacy and FIP for external communication, initiate training programmes, and deliver on the agreed outcomes from the project plan(s). Monitoring, evaluation and review by the Advisory Board will be constant throughout the three year pilot period, after which future directions of the FIPCC will be discussed by all Stakeholders.

FIP recognises the great potential of this new initiative and looks forward to the growth and development of projects arising from this collaborative partnership.

Summer School on Molecular Modeling and Drug Design

September 10-14, 2008, Istanbul, Turkey

Contact: Mine Yarim, Yeditepe University
Faculty of Pharmacy, Kayisdagi, Istanbul Turkey,
Fax: +90 2165780068

Email myarim@summerschoolmdd2008.org

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Contact: American Chemical Society
+1 301 674 2043

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Contact: EUFEPS Secretariat, PO Box 1136
SE-111 81 Stockholm, Sweden

Email conferences@eufeps.org www.eufeps.org

The 15th Intermediate Workshop on Pharmacokinetic/Pharmacodynamic Data Analysis – A Hands-on-Course Using WinNonlin

October 12-16, 2008, Barcelona, Spain

Contact: EUFEPS Secretariat, PO Box 1136
SE-111 81 Stockholm, Sweden

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Joint Pharmaceutical Analysis Group: Advances in Pharmaceutical Laboratory Efficiency

October 16, 2008, London, UK

Special Dosage Forms – What's New with In Vitro Drug Release?

October 20-21, 2008, London, United Kingdom

Towards Improved Harmonisation in Regulating Multisource Products

October 22-24, London, United Kingdom

The current state of dissolution testing

December 2, 2008, London, UK

Contact: Secretariat, Ms Julie Churchill 3rd floor, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN

UK Fax +44 20 7572 2506

Email science@rpsgb.org www.jpag.org

7th International Symposium on Multiple Risk Factors in CVD: prevention and Intervention – Health Policy

October 22-25, 2008, Venice, Italy

Contact: EUFEPS Secretariat, PO Box 1136
SE-111 81 Stockholm, Sweden

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BIO-INTERNATIONAL 2008

Towards improved harmonization in regulating multisource products

(with pre-satellite FIP Workshop: Special dosage forms – What's new with invitro drug release? 20-21 October 2008)

22-24 October 2008 at the Royal Pharmaceutical Society of Great Britain

Presented by the International Pharmaceutical Federation (FIP), and the Royal Pharmaceutical Society of Great Britain (RPSGB) in cooperation with the American Association of Pharmaceutical Scientists (AAPS) and European Federation for Pharmaceutical Sciences (EUFEPS)

Including international speakers from FDA, WHO, Watson Pharma and AstraZeneca.

For more information contact science@rpsgb.org or call +44 (0)20 7572 2640. Alternatively visit www.rpsgb.org/worldofpharmacy/events



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