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Public-Private Partnerships and 'Le défi Americain' revisited

Prof. Daan J.A. Crommelin

LEADING ARTICLE

Le Défi Americain: The Challenge

European academic groups strive for excellence in science; pharmaceutical groups for excellence in the pharmaceutical sciences. There are several ways to measure academic success. One way is to look at the number of publications and their impact on progress in science. Figure 1 clearly indicates that Europe, scattered as it may be, is doing rather well in terms of impact when compared to our American and Asian colleagues. But, what about the ensuing economic activities? Statistics tell us that 5 of the top-ten pharmaceutical companies are Europe-based, the other 5 have their base in the USA. But with R & D activities, the balance is different. Only 17% of pharmaceutical R & D activities are performed in Europe, compared to 53% in the USA and 29% in Japan (PhRMA Annual Membership Survey, 2004). When one looks at small pharma companies, the situation is not very different. The US definitely has the lead and Europe is lagging behind. Twenty years ago these statistics were very different with Europe in a leading position. Why did this happen? The answer most often given is: the pricing of drugs in the USA is more favourable than in Europe. That means there is an economic drive. But, that is not the only factor. There is more to it: the mentality within the academic community. Among my scientifically successful academic colleagues in the USA, very few have never started or been involved in one or more start-up companies. It is part of their academic scientific business, it is part of the mission of academic institutions. This long-term tradition has also created the financial infrastructure for these developments. Venture capitalist driven initiatives have flourished. And the money required was partly provided by European institutions. In Europe we have, 'grosso modo', not followed that strategy. Academic and industrial activities were more separated. 'It was not done', as an academic, to pursue transformation of academic concepts into products. The lack of financial and legal infrastructures was the result and not the reason for lack of success. A number of originally European inventions were developed and commercialised in the USA. Can we change this trend? In other words can we find in Europe an answer to 'le défi americain', the American challenge, a theme already addressed in the famous book by the French author and politician Servan-Schreiber published in 1967. Can we find an answer for Europe, culturally and economically divided as it is? This contribution briefly discusses a number of issues that may help to successfully deal with 'le défi americain'.

Academic Excellence and Industrial Success

There are differences in Europe with regard to the relationship between academic research centres and industry. Table 2 indicates that in Sweden, Denmark and the UK, industrial activity as a percentage of expenditure in the pharmaceutical/biomedical field is considerably higher than elsewhere in Europe. The UK, Denmark and Sweden are also among the high

scoring countries with regard to scientific impact (table 1). Is this the key to success? Good academic and industrial research go together? If that is the solution, what can we do to regain momentum in pharmaceutical R & D in Europe? To turn a 'brain drain' into a 'brain gain'? To turn the transatlantic flow of money around?

University Leadership

The European academic system should be sensitised to the idea that striving for commercialisation of academic research is part of the mission of universities. Not in and through academic groups. These groups should excel in their field of the pharmaceutical sciences. Academic research should lead to new concepts. To develop a pharmaceutical product from a concept is not an academic responsibility. To sensitise the scientists is one thing, to make the academic leadership appreciate and support these efforts is a second challenge. My colleagues in the USA bring in a lot of dollars to their universities by their industrial activities, be it through upfront money, milestone payments or royalty payments. They also personally benefit from these endeavours. Is that good? It certainly gives an extra drive. A professional business attitude, based on realism and familiarity with business ground rules, is a first requirement for the university leadership. Only leadership appreciating that excellence in sciences goes together with a strong academic-industry link should be chosen. This also implies that in the quality assessment of academic groups, the academic-industry interaction should be factored in.

Table 1
Worldwide rankings based on publication output and citation impact, 1998-2001

	Production of research articles		Relative citation impact of articles*	
United States	1,269,036	1	1.42	2
United Kingdom	354,724	2	1.21	4
Japan	337,810	3	0.85	18
Germany	313,712	4	1.09	9
France	231,550	5	1.01	13
Canada	164,182	6	1.21	5
Italy	150,013	7	0.95	17
Russia	127,965	8	0.32	29
China	115,403	9	0.41	27
Spain	106,023	10	0.85	19
Australia	103,648	11	1,01	12
The Netherlands	93,129	12	1.25	3
India	73,787	13	0.37	28
Sweden	72,469	14	1.13	8
Switzerland	65,878	15	1.44	1
South Korea	57,399	16	0.65	21
Belgium	47,685	17	1.09	10
Israel	46,336	18	1.06	11
Taiwan	44,457	19	0.65	22
Poland	43,518	20	0.55	24
Brazil	43,373	21	0.55	25
Denmark	37,086	22	1.17	6
Finland	34,371	23	1.15	7
Austria	33,854	24	0.98	15
Norway	23,195	25	1.01	14
Turkey	23,013	26	0.44	26
Greece	21,736	27	0.71	20
Mexico	21,014	28	0.60	23
New Zealand	20,961	29	0.96	16
Ukraine	20,304	30	0.28	30

* The citation impact is normalised for the worldwide average per discipline. This is the average number of citations received by all research articles in the professional journals (worldwide average*). Self-citations of researchers of their own articles are excluded.

Source: CWTS/ISI. Adjusted by CWTS

Technology Transfer

Concept development leads to patent applications and the university should have mechanisms to support patent submission and to do its part in the process of value creation from this know-how by industry. In my experience, technology transfer offices at universities are not the most flexible and inventor-friendly institutes. The culture is still too much 'us against them'. One reason I can see is lack of respect from the side of the scientist for the legal expert who runs away with 'his baby'. Another is the lack of feeling of technology transfer officers for the mindset of basic scientists and the typical academic culture. In the section on Education and Training, I will offer some solutions.

Transparency

Then the issue of 'transparency'. Flexibility in an academic system, where value creation is taken as part of the mission, is essential and here again leadership is required, as a primary human reaction such as jealousy can be detrimental to the performance of research groups. Total transparency of procedures and agreements is a prerequisite so that there is a firm basis for discussions on perceived unfairness and possible conflicts of interest.

Education & Training

An interesting hybrid set of skills is required to successfully run a high tech pharmaceutical business. A basic understanding of scientific concepts and academic culture is definitely an advantage. Therefore, that hurdle is low for entrepreneurs with a PhD in science. It just makes it easy to communicate and understand the intricacies of the academic science world. But, at present, relatively little attention is paid at the Master and PhD training levels to the managerial, financial and legal (e.g. intellectual property) structure in the high tech pharma industry. This could be attributed to lack of expertise in the academic world and the difficulties in bringing in experts from outside. Here lies a challenge for both the academic and industrial world: to set up education and training programmes for workers in the high tech pharmaceutical industry and... technology transfer officers to bridge the gap.

From Concept to Product: Filling the gap

How to give this process: 'from concept to product' a smooth ride? Prerequisites are excellence in science, a determined academic

management and interest for new concepts from the pharma and biotech industry. A stimulation programme should consist of a number of supporting elements, each for a specific stage of the process. It is essential to take into account the long horizon of pharmaceutical research. Typically, a full drug development programme takes 10+ years and those who design financial support programmes should be aware of this long horizon. An interesting development is the appearance of Public Private Partnerships (PPPs). The Dutch Top Institute Pharma (TIPharma) just started and is an example of such a PPP. Academic and industrial groups submit projects to this virtual (so no 'bricks and mortar') institute. The projects must have a pre-competitive, translational character and are financed (60 million euro/year) via a 1-1-2 mechanism: the academic and industrial groups are committed to bring in 25% each and the Dutch government 50% of the funding. The funding mechanism has a multiplier effect which makes it attractive for each group. This initiative brings the academic and industrial world together in an early stage of research: concept development with a strong translational character: 'from bench to clinic'. Later, the industry will work on the development of interesting concepts or spin-offs can be set up for value creation purposes. For this later development stage, other supporting mechanisms are available resembling the American SBIR (small business innovation research) program. With increasing competitiveness the subsidy level decreases.

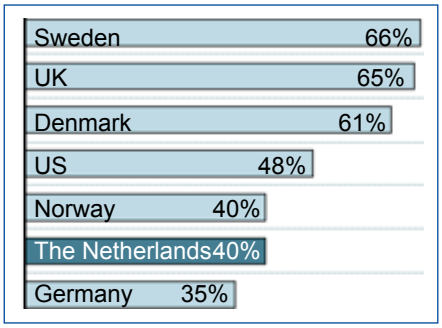
Subsidy schemes can be set up via national initiatives. Why not set up PPPs along the lines of a Dutch Top Institute Pharma, but then within the framework of the EU? An European Top Institute Pharma in the seventh framework programme of the EU? Will the Innovative Medicines Initiative (IMI) evolve into a PPP structure?

Conclusion

Le défi americain: the American challenge. It is clear, Europe has the strong science base that is needed. But, presently the set-up of a coherent response to the challenge is more a national than an EU initiative. This should change! PPPs may be part of the answer. PPP stands for Public Private Partnerships, but one can also read: Profit for the academic world, Profit for the private industry and Profit for our economy and society.

Prof. Daan J.A. Crommelin
Dutch Top Institute Pharma
Leiden, The Netherlands

Table 2. The participation of Industry in medical/pharmaceutical research



European Scientific Federations and Associations in New Collaboration

On June 11, 2006, Presidents of several European Federations and Associations, representing European learned societies and scientific communities, met in Vienna, Austria, to discuss future collaboration. All have members engaged in science, research, training and education, which are highly relevant to new drug discovery, development and evaluation.

The President of EUFEPS (the European Federation for Pharmaceutical Sciences) had taken the initiative to call the meeting. Invited Presidents represented EACPT (the European Association of Clinical Pharmacology and Therapeutics); EAPB (the European Association of Pharma Biotechnology); ECRIN (the European Clinical Research Infrastructures Network); EFB (the European Federation of Biotechnology); EFMC (the European Federation of Medicinal Chemistry); EPHAR (the Federation of European Pharmacological Societies); ESCP (the European Society of Clinical Pharmacy); EUROTOX (the European Federation of Toxicologists & European Societies of Toxicology); FEBS (the Federation of European Biochemical Societies); and GA (the Society for Medicinal Plant Research). In the meeting, it was agreed that ESF/EMRC (the European Science Foundation/European Medicines Research Councils) and ELSO (the European Life Science Organisation), newly established, should also be invited to join.

Missions, roles and activities of the participating organisations were presented at the meeting. All present strongly supported additional steps towards joint actions. Speaking (up) with one voice on relevant scientific and research matters would demonstrate a united commitment to solving problems and setting priorities for both short- and long-range new developments. Stakeholder input to the current European Innovative Medicines Initiative (IMI), established by the European Commission and industry, through EFPIA (the European Pharmaceutical Industries and Associations), has been provided by many of those represented at the Vienna meeting; more input and support would be welcome, it was reported. The meeting concluded that a Letter of Intent should be drafted about this new collaboration initiative, for further discussion of aims, mission, organisation etc. of a European Scientific Communities Leadership Group, in the boards and executive committees of the partner organisations. The Executive Director of EUFEPS was asked to draft a short report on the outcomes of the meeting, as well as to circulate an agenda for and set up a next planning meeting, preferably on October 1, 2006, in Leiden, The Netherlands (near Amsterdam airport).

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Website addresses of above organisations			
EACPT	www.eacpt.org	EPHAR	www.ephar.org
EAPB	www.eapb.de	ESF/EMRC	www.esf.org
ECRIN	www.ecrin.org	EUFEPS	www.eufeps.org
EFB	www.efb-central.org	EUROTOX	www.eurotox.com
EFMC	www.efmc.info	FEBS	www.febs.org
ELSO	www.elso.org	GA	www.ga-online.org
ESCP	www.escpweb.org		

How to develop academic drug research in Europe

Prof. Rodolfo Paoletti

In this article, Professor Paoletti, formerly an Executive Committee member of EUFEPS and long-term contributor to the EUFEPS Committee on Academic Research Relations, gives his views on important future developments in the academic institutions, which are a core element of pharmaceutical sciences in Europe.

Rapid Development and Restructuring

The pharmaceutical sciences are currently undergoing rapid development and major restructuring. The revolution of molecular biology and progress in mapping the human genome have created new challenges and opportunities for drug research covering all aspects from discovery to clinical use of drugs. To meet the challenges, there is a pressing need for pharmaceutical scientists with interdisciplinary training coupled with an academic and industrial research perspective.

Enormous Potential to Exploit

Unleashing the full potential of European universities is a key part of the Lisbon Strategy to create jobs and growth in Europe. With 4 000 institutions, over 17 million students and some 1.5 million staff - of whom 435 000 are researchers - European universities have enormous potential. However, this potential is not fully exploited and is not working effectively to strengthen Europe's drive for more growth and more jobs. Universities also have to accept that research is no longer an isolated activity and that the emphasis is shifting from individual researchers to teams and global research networks. Scientific problems tend to go beyond traditional disciplinary structures: cutting-edge research is increasingly being conducted at the interface between academic disciplines or in multidisciplinary settings. Universities' research environments are more competitive, globalised and require greater interaction.

Process Approach Preferred

Academic groups have traditionally worked on one aspect of the drug discovery or development process. Pharmacology or pharmaceutical technology departments in academic centers defined their own research goals and worked in more or less splendid isolation. While they were small, this has led to important new findings and an understanding of basic mechanisms. The idea of following the industrial pipeline approach for creating new drugs was neither appreciated nor followed. Nowadays, one can observe trends towards increasing group size in order to reach a critical mass, focusing research on particular subjects and structuring academic drug research institutes more along the lines of industrial operation: the drug pipeline including the feedback loops. This process is driven, for example, by advice from internal and external review panels and by networks. Currently, research institutes concentrating entirely on different aspects of drug research can be found in selected European countries including Denmark and the Netherlands.

Despite the willingness of the universities to spin off their expertise, encouraged by national governments, Europe is facing a knowledge paradox: academic research groups do an excellent job, but the activities, business and products resulting from this are limited. Further attuning of research directions and stimulation of academic drug research through innovation platforms, both at the national and international level, is required. For instance, centers for Good Manufacturing Practice (GMP)-production of biotechnological drugs (antibodies, vectors, cell therapies) are needed. Several deficiencies hamper the drive for innovation in healthcare;

- a lack of qualified people
- insufficient start-ups from universities
- an inadequate clinical biotechnical research structure in most academic centers
- slow introduction of biologicals
- a lack of funds.

EMEA Important Role

Current regulation is not able to cope with new developments. The European Medicines Agency (EMEA) is the main drug regulation and registration agency in Europe, and so decisions of the EMEA should quickly apply to individual countries.

Intellectual Property in Focus

A more professional approach towards protection of intellectual property by academic medical centers is important just as is a more professional approach towards seed capital funding for biotechnological companies. Some fifteen years ago, a good publication in a high-level scientific journal used to be the start of a small company. Experience has shown that it is not that easy any more. The intellectual property rights that gave rise to such a start-up company should in future stay in the parent institution. It is of great importance that intellectual property becomes a focus in the process of drug development, together with the experience of the employees. Universities cover both the educational and the research aspects, which make them the ideal place for this focus. The education system needs to be adapted to the current multidisciplinary approach in drug development. Many new people are not trained in a multidisciplinary way, but focus on one area. Teaching them to focus on multiple areas can increase these people's productivity. In addition, medical schools and teaching hospitals have largely abdicated their responsibility to educate physicians, leaving that to drug companies. To solve these problems the training of clinicians should be improved: more emphasis should be laid on molecular pathology, biotechnology and on drug development/regulation. This will stimulate innovation in drug research.

Drug Development Challenges

Drug companies often concentrate on producing minor variations of top-selling drugs already on the market – called "me-too" drugs. Most of the research and development funding goes into clinical

trials, the last stage of drug development. Innovative drugs are much rarer and stem from publicly funded research at university and government laboratories. Yet much industry-sponsored clinical research is carried out at academic medical centres. Studies show that such research is more favourable toward the sponsors' drugs than publicly funded research, and it is often biased in design – e.g., a clinical trial may compare a new drug with a placebo, when what doctors really want to know is how it compares with an old drug. GCP, Good Clinical Practice, is an international set of ethical and quality standards that applies to medicinal trials in humans. These standards indeed relate to research and have been in effect for many years pertaining to all trials intended to generate data for marketing authorization procedures whether they be new medicinal products or line extensions for already marketed products. As a general rule, academic research involving already marketed products and not intended to generate results for marketing authorization purposes has been exempt from these rules. Yet within the EU, these rules, as of May 1st 2004, pertain to any medicinal trials in humans, including those involving already marketed drugs and trials performed without industry engagement. This represents a serious challenge to the academic independent drug related research, as systems to assure GCP compliance must be developed, which in turn requires allocation of appropriate resources.

European Diversity Benefits

Modernisation of Europe's universities, involving their interlinked roles of education, research and innovation, has been acknowledged not only as a core condition for the success of the broader Lisbon Strategy, but as part of the wider move towards an increasingly global and knowledge-based economy. The European dimension offers the potential benefits of larger scale operation, greater diversity and intellectual richness of resources, plus opportunities for cooperation and competition between institutions. In this respect, the European Commission has already proposed the establishment of the European Institute of Technology (EIT). This new organization could contribute to improving Europe's capacity for scientific education, research and innovation, while providing an innovative model to inspire and drive change in existing universities, in particular by encouraging multi-disciplinarity and developing the strong partnerships with business that will ensure its relevance. Interaction with the outside world will gradually make universities' activities more relevant to the needs of citizens and society at large. It will help universities to promote their different activities and to convince society, governments and the private sector that they are worth investing in.

Urgent Modernisation Needed

Universities are key players in Europe's future and for the successful transition to a knowledge-based economy and society. However, this crucial sector of the economy and of society needs in-depth restructuring and modernisation if Europe is not to lose out in the global competition in education, research and innovation.

Prof. Rodolfo Paoletti
University of Milan, Italy

The Innovative Medicines Initiative (IMI) – Latest News

Unique Collaboration

IMI is the unique pan-European collaboration between large and small biopharmaceutical companies, academia, regulatory agencies and patients to support faster discovery and development of new medicines. IMI provides clear practical paths to accelerate the discovery and development of innovative safe medicines, which can reach patients faster. The initiative represents a co-ordinated public-private collaboration to boost Europe's biomedical and pharmaceutical R&D base, correcting the relative under-funding of this sector in Europe compared to other regions of the world.

Will Fly

From the recent Presidency Conference on European Technology Platforms, it appears likely that the Innovative Medicines Initiative (IMI) will fly.

The arguments in favour are

- IMI will probably be on the shortlist of 3 Joint Technology Initiatives
- IMI is one of the mature platforms
- High stakes on IMI from both EC and EFPIA including the credibility of EC towards the pharma industry and the EFPIA/Industry credibility towards the EC and the public image
- Many regions in Europe are now active with IMI relevant initiatives

Timeline

FP7 proposal has **just** been submitted to Council & Parliament. In **October 2006,** Council & Parliament approves FP7. In **November 2006**, Council approves the specific programme, and then EC submits IMI to the Council.

Thus **before the end of 2006,** we should have a decision on the IMI.

Engage

For the sake of the pharmaceutical sciences in Europe, it is important that all of you use your contacts to local government to lobby for a positive attitude towards IMI, in the face of fierce competition from other technology platforms.

Website

Read about the Innovative Medicines Initiative (IMI) at:
www.europa.eu.int/comm/research/imi.html

You may also contact Hans H. Linden of the EUFEPS Secretariat at:
hans.linden@eufeps.org

Many attended this recent EUFEPS Conference in Verona, Italy.

Conference Report

When poor solubility becomes an issue: from early stage to proof of concept

EUFEPS sponsored this conference, which took place in Verona (Italy) on April 26-27, 2006. Contributors to this conference were: G. Amidon (University of Michigan, USA), H. Benameur (Capsugel, France), M. Brewster (Janssen, Belgium), C. Caramella (University of Pavia, Italy), W. Charman (Monash University, Australia), P. Connolly (GSK, UK), J. Dressman (Goethe University, Germany), E. Frijlink (Groningen University, Ntherlands), B. Henry (Pfizer, UK), J. Lawrence (Kings College London, UK), L. Lindfors (AstraZeneca, Sweden), D. Papoutsakis (Novartis, USA), R. Patterson (AstraZeneca, UK), M. Richelle (Nestle Institute, Switzerland), W. Smith (Pfizer, USA), C. Spancake (GSK, USA), V. Stella (University of Kansas, USA), J. Van Gelder (Lilly, Belgium), W. Weitschies (Ernst Moritz Arndt University, Germany), I. Wilding (Ian Wilding Associates Ltd, UK), I. Yemen (Astra-Zeneca, Sweden), P. York (University of Bradford, UK)

Much Changed

Sufficient and reproducible bioavailability in humans is recognised today as one of the major challenges in oral delivery of new drug compounds. The issue arose mainly when drug discovery and medicinal chemistry moved from wet chemistry to combinatorial chemistry and high throughput screening, in the mid 1990s. With the introduction of combinatorial chemistry and high throughput screening, the properties of new chemical entities shifted towards higher molecular weight, increasing lipophilicity and, as a consequence, decreasing aqueous solubility.

Taking into account the drug product development times of 8 – 12 years, the R&D productivity gap, as indicated by products in late stage clinical development today, is the result of the drug discovery and formulation development in the late 1990s, which were the early and enthusiastic times for combinatorial chemistry and high throughput screening.

In parallel with the implementation of these new technologies, tremendous knowledge has been accumulated on biological factors impacting bioavailability such as metabolising enzymes, transporters and efflux systems, as well as on physicochemical factors of drug substances such as crystal structures and salt formation. With the accumulation of this knowledge, tools and technologies have been, are and will be, developed to evaluate the impact of these factors for new chemical entities.

Aqueous Solubility Important

When looking to the product launches between 1995 and 2002, out of 100 compounds 14 were considered class I, 12 were classified as class II, 28 were class III and 46 were class IV compounds (Mehta M. 2002). Whether poor solubility causes an issue for product development depends on complex interactions of various physicochemical and biopharmaceutical properties as well as the targeted dose. Today, about 35 – 40 % of the lead compounds are known to have an aqueous solubility of less than 10 µM or 5 mg/ml at pH 7, and it is not expected that this figure will change in the future.

The conference focused specifically on poor aqueous solubility of drug compounds, its impact on analytical evaluation, predic-

tion of oral bioavailability, compound selection, formulation strategies and development. The existing tools and technologies, their potential utilisation throughout the drug development process and the directions for further research to overcome existing gaps were discussed in detail.

Solubility in different solvents is an intrinsic material characteristic for a defined molecule. To achieve a pharmacological activity, the molecules must exhibit certain solubility in physiological intestinal fluids to be present in the dissolved state at the site of absorption. The aqueous solubility is a major indicator for the solubility in the intestinal fluids and potential contributions to bioavailability issues.


Session Chairman...


... young generation...

Find out Early

During drug compound development, the molecules are screened in receptor assays at nanomolar concentrations. The molecules with the best receptor binding are selected for further pre-clinical studies, for which more drug compound is synthesised. Already at this stage, solubility is of critical importance, because solubility estimates of this poorly specified drug substance are used to set up and evaluate the pharmacological and toxicological profiling of the drug compound.

For first-in-human studies, sufficient and well characterised solubility becomes even more critical. From now on, the solubility or dissolution in the varying physiological media, to which the drug compound or formulated drug compound will be exposed, are expected to be reproducible and remain unchanged for the final development and possible marketing.

It is well accepted today throughout the scientific community that drug compound solubility, and especially aqueous drug compound solubility, is an issue for the drug discovery as well as the early and late stage pharmaceutical development processes and therefore needs to be addressed very early on, during the drug candidate selection process.

How to Alter and Predict?

The solubility or dissolution of the drug compound can be mainly altered on two levels, through material engineering of the drug compound or through formulation approaches. Whatever route is taken to enhance or modify the solubility and/or dissolution of a lead compound, it needs to be scalable to a commercially viable process later on in the development.

Material sciences groups are looking very closely into drug substances and their most suitable forms for development, in terms of stability and solubility. Early assessment of each new drug, and sometimes, experimental formulation work, is conducted to ensure solubilised drug in the pre-clinical assays. Various computational tools allowing rough predictions on the possible crystal forms of the drug, as well as on its *in vivo* performance, support drug development. Formulation strategies for the clinical and commercial phase are investigated early on, when bioavailability issues are identified. Solubility enhancing formulation approaches have been developed and continue to evolve. More sophisticated work is under way to better understand the physiological conditions of the GI tract and the underlying processes of drug absorption, which will lead to both, better *in vitro* evaluation and prediction tools, as well as to more targeted drug delivery systems.


... and members of the Scientific Programme Committee.

Tremendous Progression Foreseen

Understanding the different root causes for poor or highly variable oral bioavailability of a drug compound is key to addressing the problem. Limited drug compound solubility in the physiological conditions of the GI tract is well known to be one of the main root causes. New tools and technologies have been developed and introduced into medicinal product development that substantially address the solubility factor early on as part of the lead candidate selection process. Continuous scientific evolution also makes us aware of the complexity of identifying and developing innovative therapies for unmet medical needs. An interdisciplinary approach of medicinal chemistry and pharmaceutical sciences from academia and industry is extensively practiced. This led and will lead to tremendous progression in bringing new and innovative products to market, but its perception by the community will lag behind due to the pure focus on today's pipelines of clinical products.

S. Stegemann, F. Levellier, D. Franchi, H. de Jong, and H. H. Lindén

Reference;
Mehta M.: AAPS/FDA Workshop on Biopharmaceutics Classification System. September 25-27, 2002

Executive Report • June 2006

The year 2005 was a successful one for EUFEPS, and the first half of 2006 has been as well, also financially. There is more progress.

EUFEPS Meetings and Courses

The success includes EUFEPS' own meetings programme, i.e. the one *organised* by EUFEPS as well as the PharmSciFair and other EUFEPS *co-organised* and *co-sponsored* events, all providing new and unique platforms for pharmaceutical scientists to meet to report on progress, to learn new things, to network with colleagues and to agree on new research goals and objectives. Certainly, the pharmaceutical industry, big and small, is taking advantage of them, and one would like to see far more academia and regulatory doing this as well. It is in the mission of EUFEPS to bridge between and to help to join forces, in the interest of the pharmaceutical sciences and scientists.

The first EUFEPS Conferences in 2006, on *Optimisation of Drug-Like Properties of Leads in Discovery: Fine-Tuning the Physchem-Biopharmaceutical-ADME-Tox Profile*, in the beginning of March in Zurich, attracted 180 delegates, and the second one, on *When Poor Solubility Becomes an Issue: From Early Stage to Proof of Principles*, in the end of April in Verona, had 290 delegates, including around 30 students enjoying the free "Student Package" for which sponsorship had been raised. The Verona meeting was the first one by EUFEPS set up in an industrial setting, in the excellent conference centre of GSK Verona. The 5th advanced Course on *High-throughput Drug Metabolism*, at the end of May in Amsterdam, got 17 participants, most of them representing industry, which is the opposite distribution, more or less, compared to the first one in 2002.

Four bigger events are scheduled for the second half of 2006 and in early 2007. They are:

- *Membrane Drug Transporters: Impact on Drug Discovery, Development, Regulation and Usage*, on September 25-27, 2006, in Copenhagen, Denmark;
- *EuPAT 1 on Scientific Progress Underpinning Process Analytical Technology (PAT)*, on November 21-22, 2006, in Göteborg, Sweden, in collaboration with the Nordic Affiliate of the International Society of Pharmaceutical Engineering (ISPE);
- *Effective Integration of Systems Biology, Biomarkers, Biosimulation and Modelling in Streamlining Drug Development*, on November 29-December 1, 2006, Basel, Switzerland – in close collaboration with the BioSim Network of Excellence (see below), and co-sponsored by the Swiss Society of Pharmaceutical Sciences (SGPhW), the European Center for Pharmaceutical Medicine (ECPM), and the American College of Clinical Pharmacology (ACCP);
- *Optimising Biotech Medicines: Second-Generation Pharmaceutical Proteins*, in January 2007, in Munich, Germany (preliminary), in collaboration with German Pharmaceutical Society (DPhG).

For aims, objectives, who should attend, preliminary programme, venue, fees, registration and accommodation procedures etc., see circulating announcements and "Current Meetings" of the EUFEPS Online at: www.eufeps.org For alerts on forthcoming events, also access the EUFEPS Online and/or join the community receiving the electronic "EUFEPS Flash" by sending a registration email to: annika.nyman@eufeps.org It is a service for free.

Next PharmSciFair and PSWC 2007

The next full-size *PharmSciFair* (Pharmaceutical Sciences Fair & Exhibition) is scheduled three years from now, for June 7-12, 2009, also in Nice, France. Partners of the first PharmSciFair have started considering how to engage, and there will be room, in the 2009 one, for additional partners to engage. If interested in setting up a programme, in sponsoring this new joint European meetings platform or in exhibiting at it, contact the EUFEPS Secretariat, and we'll bring it up with the 2009 PharmSciFair Planning Team.

As reported, there will be no PharmSciFair in 2007, because of the *3rd World Congress of the Board of the Pharmaceutical Sciences of FIP (PSWC 2007)*, on April 20-27, 2007, in Amsterdam, including a *Pre-Satellite Meeting*, for and by Students, and a *Post-Satellite Workshop*, on Monoclonal Antibodies, respectively. At it, there will also be a *PSWC 2007/PharmSciFair Exhibition* and a number of *EUFEPS Afternoon Sessions*, picking up the successful idea from the EUFEPS 2002 in Stockholm, Sweden. EUFEPS is co-sponsoring the PSWC 2007 and also engaged in the organisation and promotion of it. For detailed information on it all, see circulating announcements and consult the PSWC 2007 Website at: www.fip.org/pswc

Research Stream

Both in 2005 and in the first half of the 2006, EUFEPS played an important role in supporting and promoting the new Innovative Medicines Initiative (IMI), in close collaboration with the European Commission and the EFPIA (European Federation of Pharmaceutical Industries and Associations), as extensively reported in e.g. the March 2006 issue of this NewsLetter. There is an update on page 5 of this one. As the Commission budget for research, including for the 7th Framework Programme for Research and Technological Development, is now there, it remains to settle budget and governance structures etc. of the new European Technology Platform, by the Commission, primarily, in collaboration with the IMI "Country Group".

Additional projects in the EUFEPS "basket of research projects", funded by the European Commission, include contributions to the IMI/InnoMed Research Project, the BioSim Network of Excellence, and the EUMAPP, respectively (for links to websites on aims, organisation and progress etc., see "New Safe and Innovative Medicines Initiatives" of the EUFEPS Online at: www.eufeps.org).

Membership Development

In membership development, forming new networks and opening up a new membership category of EUFEPS made substantial progress.

In addition to the Partner Networks for the PharmSciFair and for the BBBB Conference Series, respectively, there are two Membership Networks established and two emerging. They are:

- *Network on Safety Sciences* – established in spring 2004 (in Brussels) but not yet very active, due to very busy high-level leadership;
- *Network on Process Analytical Technology (PAT) Sciences* – established in fall 2004 (also in Brussels) having a very active Steering Group, engaging in several events, including in setting up the first EuPAT 1 Conference (see above);
- *Network on Biopharmaceutics and Bioavailability Sciences* – established in 2006 (in Frankfurt, a couple of months ago), also having started organising a leadership group and planning future activities; and a
- *Network on Pharmacogenetics/Genomics/Personalised Medicines Sciences* – to be

established at a first Workshop on the topic/s for invited experts, in November 2006, in Utrecht, The Netherlands.

There are additional ideas of networks to be formed, so more will materialise in years to come, I think.

At the EUFEPS Council in September 2005, in Siófok, Hungary, the EUFEPS Executive Committee asked the Council's approval of plans to establish a new membership category of EUFEPS, one of *Universities and Research Institutions*. In the last few months, this resulted in a first round of invitations to around 25 European Universities and Schools of Pharmacy to join EUFEPS. This membership of EUFEPS would, the Executive Committee stated, provide an even more influential platform for future research funding of pharmaceutical sciences in Europe; a unique university network or cluster for drug research, development and evaluation, including e.g. information exchange and coordination and collaboration towards European specialist training (courses) and master level programmes; and insight into long-term European ambitious programmes and plans, including funding application material, perhaps, even before it will be publicly available to allow early and proactive preparation. In other words: They should "Go European with EUFEPS"!

New European Forum

As reported, setting up a number of working parties was also discussed and approved at the Siófok Council meeting, including a "WP Forum" on how to create a forum for European (sister) federations and associations of EUFEPS, i.e. those having members engaging in sciences and disciplines relevant for drug discovery, development and evaluation. To bring it up with them, the President of EUFEPS invited ten fellow Presidents to a meeting on June 11, 2006, in Vienna, Austria, in conjunction with the latest Executive Committee meeting and the EUFEPS President's Conference (see below). For a brief report on the successful outcome of the "forum meeting", see page 3.

EUFEPS President's Conference

Obviously, there was also a "President's Conference" for Member Societies of EUFEPS, in conjunction with the recent Vienna Executive Committee meeting. The outcome of this important meeting was immediately communicated in the electronic "EUFEPS Membership Bulletin", to all Individual Members and the Member Society Leadership of EUFEPS. Representatives of 12 European countries were present at this extremely fruitful meeting, it stated. The meeting provided a lot of input for the EUFEPS next Strategic Plan (2006-2010), which will be presented and discussed during the next Council Meeting at the end of September, in Copenhagen. In the Membership Bulletin, all members were, furthermore, asked to send input to the new Strategic Plan (for the current strategic plan, see "Mission and Strategy" of the EUFEPS Online).

Next Executive Meetings and Council

Executive Committee meetings since the 2005 Council include: November 18-19, 2005, in Stockholm, Sweden; March 3-4, 2006, in Zurich, Switzerland; and June 9-10, 2006, in Vienna, Austria. The Executive Committee will meet next on both the day before and on the day after the next Council Meeting and Open Forum, which will be held on September 24, 2006, in Copenhagen, Denmark.

Hans H. Lindén
Executive Director, EUFEPS
Email hans.linden@eufeps.org

Integrating systems biology, biomarkers, biosimulation and modelling in streamlining drug development

As indicated, this is theme of the next Conference in the successful EUFEPS Series on Optimising Drug Development in Basel, Switzerland – this year on November 29-December 1, 2006 (see the Executive Report, pages 8-9).

What is it?

To increase the efficiency and productivity of new drug development, new tools for predictive human models of disease and efficient drug discovery, development and evaluation are necessary. Among these new technologies, "modelling", "biomarkers", "biosimulation" and "systems biology" are gaining increasing attention. What would be visionary and effective integration of them all?

For example, modelling is applied in drug development to predict the outcome of the next steps to be taken in various processes. Biomarkers will enable translational data from preclinical species to humans, hence helping to understand drug effects, side effects and toxicity in a more predictive manner. Quality in data is a must for successful submission to regulatory authorities, arrived at by careful study design and validation. Biosimulation is, furthermore, an old dream of in silico pharmaceutical sciences. Core activities would include translation of experimental insights into consistent mathematical frameworks, including formal models to predict the course of physiological processes under varying conditions. Systems biology approaches are expected to link genomic, proteomic and metabolomic data and bioinformatics, to provide better understanding and simulation of function and dysfunction of living systems. New insights will change paradigms of drug discovery, development and evaluation.

Who should attend?

The Conference is intended for drug discoverers, developers and evaluators, including in silico, in vitro and in vivo scientists, clinical pharmacologists and other scientists exploiting modelling, biomarkers, biosimulation and systems biology, as well as for academic researchers who want better insight into industry use of these approaches, e.g. to become aware of urgent training needs, and for regulator and patient group scientists evaluating today's and tomorrow's medicines therapy.

Who will contribute?

For the Preliminary Programme, including sessions and expert speakers, see circulating announcements and "Current Meetings" of the EUFEPS Online at: www.eufeps.org or contact the EUFEPS Secretariat, P.O. Box 1136, SE-111 81 Stockholm, Sweden. Tel +46 8 7235025. Fax +46 8 4113217. Email conferences@eufeps.org

26th International Symposium on Chromatography
August 21-15, 2006, Copenhagen
Contact: ICS'06 Symposium Secretariat
Universitetsparken 2, DK-2100 Copenhagen
Denmark, Email shh@dfuni.dk, www.isc06.dk

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European Pharmacopoeia: Symposium on Impurities Control for Antibiotics and Peptides
September 21-22, 2006, Strasbourg, France
Contact: www.pheur.org/site/page_598.php

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Membrane Drug Transporters: Impact on Drug Discovery, Development, Regulation and Usage
September 25-27, 2006, Copenhagen, Denmark
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Email secretariat@eufeps.org , www.eufeps.org

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3rd Santorini Conference: From Human Genetic Variations to Prediction of Risks and Responses to Drugs and the Environment
September 29 – October 2, 2006, Santorini, Greece
Contact: Biologie Prospective, Inserm U525
30, Rue Lionnois, FR-54000 Nancy, France
Email Gerard.siest@pharma.uhp-nancy.fr
www.biol.prospective-conf.u-nancy.fr

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Symposium on the New Microbiology Chapters of the European Pharmacopoeia
October 2-3, 2006, Strasbourg, France
Contact: www.pheur.org/site/page_647.php

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Symposium on Requirements for Production and Control of Avian Influenza Vaccines
October 19-20, 2006, Strasbourg, France
Contact: www.pheur.org/site/page_597.php

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QA, QC; GXP for Pharmaceutical Production
October 2-6, 2006, Copenhagen, Denmark
Non-clinical Safety and Toxicology
November 6-7 and 9-10, 2006, Copenhagen, Denmark
Biological Membranes. Drug Targets and Absorption Barriers
November 17-24, 2006, Copenhagen, Denmark
Contact, for all three: Elsebeth Bech
The Danish University of Pharmaceutical Sciences, 2, Universitetsparken, DK-2100 Copenhagen, Denmark, Email elb@dfuni.dk
www.dfuni.dk/postgrad-courses

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Drug Metabolism with a Medicinal Chemistry Perspective, 6 ECTS credits
Part one November 6-9, 2006.
Part two: December 4-6, 2006, Rimbo, Sweden
Contact: A Lindberg, Swedish Academy of Pharmaceutical Sciences, Box 1136
111 81 Stockholm, Sweden
Fax +46 8 205511
Email annette.lindberg@lakemedelsakademin.se
www.lakemedelsakademin.se

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Scientific Progress Underpinning Process Analytical Technology (PAT)
November 21-22, 2006, Göteborg, Sweden
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org , www.eufeps.org

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EUFEPS Conference on Optimising Drug Development: Effective Integration of Systems Biology, Biomarkers, Biosimulation and Modelling in Streamlining Drug Development
November 29-December 1, 2006, Basel, Switzerland
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org , www.eufeps.org

Optimising Biotech Medicines: Second-Generation Pharmaceutical Protiens
January, 2007, Munich, Germany (preliminary)
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org , www.eufeps.org

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PSWC 2007 Pre-Satellite: Young Pharmaceutical Scientists Meet in Amsterdam
April 20-21, 2007, Amsterdam, The Netherlands
Contact: S.C. De Smedt , Ghent University
Faculty of Pharmaceutical Sciences
Harelbekestraat 72, 9000 Gent, Belgium
Fax +32 9 2948189
Email stefaan.desmedt@ugent.be
www.pharmacie.univ-lille2.fr/presatellitePSWC

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3rd FIP Pharmaceutical Sciences World Congress (PSWC 2007)
April 22-25, 2007, Amsterdam, The Netherlands
Contact: FIP Congress & Conferences
P.O. Box 84200, NL-2508 AE The Hague
The Netherlands. Fax +31 70 3021998
Email pswc@fip.org , www.fip.org/pswc

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PSWC 2007 Post-Satellite: Workshop on Monoclonal Antibodies
April 26-27, 2007, Amsterdam, The Netherlands
Contact: EUFEPS Secretariat, P.O. Box 1136
SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org , www.eufeps.org

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To announce your conference, workshop and course, send breif information to the EUFEPS Secretariat. For full address, see front page.

The Institute for Pharmacy, Faculty for Chemistry and Pharmacy of the Leopold Franzens University, Innsbruck, Austria (http://www.uibk.ac.at) has a vacancy for a

University Professor of Pharmaceutical Chemistry

In the case of a first appointment, the employment contract will be for 6 years initially, and then unlimited, after a positive evaluation. In other cases, the contract will be unlimited from the start.

Field

The whole span of Pharmaceutical Chemistry is to be covered in teaching and research. The core of the research should be in the of drug development. The successful applicant should also bring their research into the Centre for Molecular Biology (CMBI).

In teaching, particular collaboration in the appropriate faculty courses is expected.

Furthermore, participation in the self-government of the university is foreseen.

Requirements

a) relevant education at a domestic or equivalent foreign university
b) appropriate teaching qualification (venia docendi) or similar achievement
c) publications in leading international journals
d) competence and experience in experimental research for drug development
e) proof of engagement in international research
f) inter-disciplinary work in the areas of chemistry and biology
g) project experience and foreign experience
h) excellent didactic skills
i) experience in attracting research funds
j) leadership qualification

Applications should be sent, before August 31, 2006, to Fakultäten Servicestelle, Innrain 52f, A-6020 Innsbruck, Austria (fss-innrain52f@uibk.ac.at)

The Leopold Franzens University aims to employ a higher number of women and so invites applications from qualified women. With the same qualifications, a female candidate will be preferred.

The application should contain: your curriculum vitae with a description of scientific and career aspirations, a list of your scientific publications and presentations as well as of current projects, a description of your research plans, documentation of your 5 most important pieces of work. The application should always be submitted electronically (CD, email, etc.), on paper is optional.

You will find current information on the status of the process at: http://www.uibk.ac.at/fakultaeten-servicestelle/standorte/innrain52f/