EUFEPS

NEWS Letter

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LEADING ARTICLE

"Times are changing and we change with time"

Reflections of the Past President and President at the turn of the year

Christian R. Noe and Daan J.A. Crommelin

"Tempora mutantur et nos mutamur in illis" – "Times are changing and we change with time". "Globalisation" is a term implying rapid change. It is associated also with the present financial-economic crisis, which demonstrates all of a sudden, that the old Latin expression is still relevant to a large extent. There is little doubt that everybody will change with time. However, with permanently and swiftly ongoing changes in the world around us, we are free to decide, when, how and to which degree we have to change our positions and ourselves. Otherwise, it will be others that will impose the changes upon us.

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.

Europe unified

The formation of a unified Europe is another process of change, slowly going on over the years. This movement is of fundamental importance for all people living in this region. It is obvious that, within the European project, positive effects of changes are by far prevailing over negative effects. EUFEPS as a federation has been founded to support the European idea. EUFEPS, representing pharmaceutical scientists and promoting the pharmaceutical sciences, has done its best to promote a common European dimension of high quality research. EUFEPS, representing scientists, has also done its best to create a truly European community of pharmaceutical scientists. Last not least, all of EUFEPS´ activities have taken place to secure sustainability of successful pharmaceutical research in the European region.

Bottom-up and top-down roles

A further aspect of changes in time are those waves in politics, which favour either democratic "bottom up" approaches or feudalistic "top down" approaches. As a matter of fact, this situation occurs not only in politics, but in almost all human organisational systems. Only a harmonised relation between "parliament" and "government" can assure justice and benefit for the population. Taking EUFEPS as an example, the "Council" would stand for the "Parliament", the "Executive Committee" would stand for the "Government". It is clear that the membership, represented by the Council, is the core of the Federation and that the Council has to act according to the wish of this membership. Being aware of this important >>>

distribution of roles, it has been the Executive Committee, which over the years has taken a series of measures to strengthen the role of membership, the rock on which EUFEPS stands. This not only led to increasing the number of member organisations or introducing the category of individual members. It also meant establishing the President´s Conference, a 'twice-a-year gathering' of the presidents of the EUFEPS member organisations. This forum should discuss initiatives and needs arising across the continent in an open debate with the EUFEPS leadership.

New initiatives strengthen

An even further reaching step was taken in view of the complexity of pharmaceutical research. The "European Pharmaceutical Sciences Leadership Forum" was established to create a platform, where the leadership of scientific organisations related to the pharmaceutical sciences meet to discuss problems, to share views, to identify areas of common interest and to co-ordinate planning on both broad and detailed levels. For EUFEPS, this forum is of particular interest, because it is the only organisation in Europe standing for pharmaceutical sciences in its full scope, comprising the main areas of discovery, development, production and utilisation of drugs (see scheme 1). It is EUFEPS´ interest to strive for the common goal of promoting top quality pharmaceutical research in Europe jointly with the other organisations. The EUFEPS Senate, made up of the best European researchers in the field, regardless their educational background, will hopefully be a particularly effective think tank reacting quickly to changes and giving answers to the needs of the pharmaceutical scientists´ community, in particular concerning the future of research. All these initiatives constitute, in principle, "top down" actions of the Executive Committee to provoke "bottom up" activities, which will strengthen the Federation and will help to reach the overall goals.

IMI now operational

As a matter of fact, the "daily" work at the executive level of EUFEPS is mainly focused on the implementation of the strategic plan as decided by the Council. This means a lot of specific activities and actions, e.g. organisation of conferences, workshops, arranging the work of the committees and networks, co-ordination of the PharmSciFair and many others. One of the most important projects, the support of the implementation of the Innovative Medicines Initiative (IMI) within the 7th Framework Programme of the EU has just been finished with the IMI starting to be operational from now on. Without any doubt, the IMI is a very promising, important and, due to the financial options, also effective "top down" instrument from the European Commission to promote the pharmaceutical sciences in Europe. Hopefully several of the present EUFEPS activities will be continued by IMI on a financially stronger basis. This will hopefully set free the required energy and capacity for important new EUFEPS Executive Committee (ExCo) activities. One of these new tasks will be to raise awareness of the potential of the IMI and to connect the instruments and activities of IMI to the EUFEPS membership.

New pharmaceutical medicine

There is one particularly important initiative within IMI, which will result in a significant change in the setting of organisations dealing with pharmaceutical sciences. Promotion of "pharmaceutical medicine" is one of the goals of IMI. The term "pharmaceutical medicine" was coined some time ago. In brief, it describes "pharmaceutical sciences" from the standpoint of medically trained scientists, just as "medicinal chemistry" describes our science from the standpoint of chemists or "pharmaceutical biotechnology" does so from the standpoint of molecular and cellular biologists. Of course, clinical drug development is at the core of pharmaceutical medicine, but it aims to be more and it should be more. It should comprise the best possible contributions that medical doctors with their educational and professional background can give to the pharmaceutical sciences. This is certainly not less relevant than the contributions from the other main disciplines. This awareness of the importance of pharmaceutical sciences within the medical community and the wish for new organisational and educational approaches have to be welcomed, in view of our ambition to promote the best possible science in Europe.

EUFEPS' mission stands

In a recent discussion within the miniExCo of EUFEPS, the opinion was shared that it is the duty of EUFEPS to support initiatives to develop the field of "pharmaceutical medicine". This will speed up implementation of new findings in the drug development process, add quality and will help to avoid duplications. Thus, the overall quality of pharmaceutical research, concerning the full drug discovery and development process, not forgetting drug utilisation (scheme 1), will increase.

Please contribute views

Of course, involvement with "pharmaceutical medicine" means a change for EUFEPS. It is however not at all a change with respect to reaching the central goal of promoting the quality of pharmaceutical sciences in Europe. Within the Leadership Forum and the Senate, contacts have already been established and will be further established with organisations from different areas and scientists of different disciplines, including medicine. The change is much more related to the question of "who are our members?" Most of our membership organisations at present are national pharmaceutical organisations. In the heart of their scientific competence is preclinical pharmaceutical development. Of course, there is also high competence in the field of pharmacotherapy and drug utilisation, due to the professional qualification associated with pharmacy education. At present, the discovery competence is shared with chemists and molecular biologists. And without any doubt, nobody would have questioned the medical competence in clinical development. Therefore, there is no major obstacle for EUFEPS to support activities aiming at the promotion of the science side of pharmaceutical medicine. As a consequence, we propose EUFEPS to open up its membership to "pharmaceutical medicine" scientists and to actively seek collaboration with European organisations, existing or to be established, in the field of pharmaceutical medicine.

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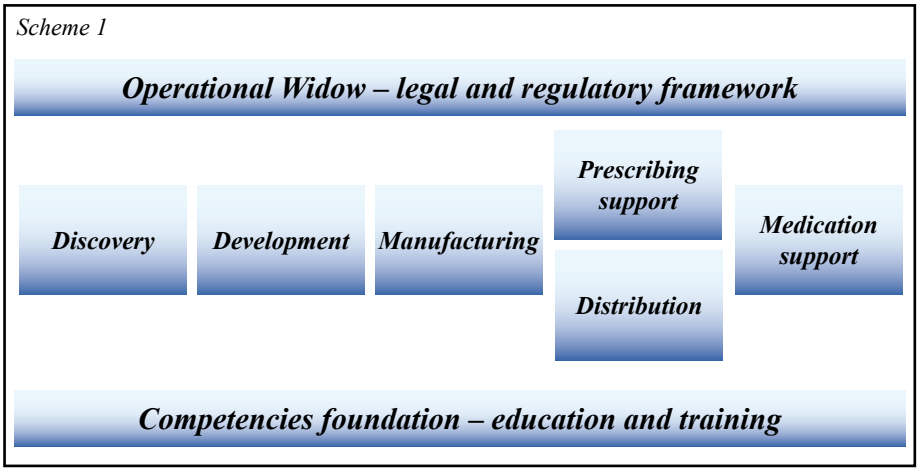
Scheme 1



>>> Some mental change might be required. The present pharmacists and pharmaceutical scientists tend to fear domination by medical doctors, and discussions on "staking of claims" and on "importance of fields and pecking order" will continue. However, such discussions seldom bear fruit. It has been the mission of EUFEPS from its foundation to serve pharmaceutical scientists and to promote and foster the pharmaceutical sciences. To us, it is in line with this motto to seek an active interaction with our colleagues in pharmaceutical medicine. Your Past-President and President look into the future with great expectations and invite you, EUFEPSonians, for comments. 'Top down' and 'bottom up' – in a strong and healthy organisation, there is this two-way street where the leadership invites its members to a debate on opinions and strategies. Therefore, ending with the Greek philosopher's version of the Latin expression cited at the beginning: "Panta rhei kai ouden menei", "everything changes and nothing remains the same" does – in mid-term perspective – apply to the "everyday life of EUFEPS", but does not apply to the EUFEPS basic principles and tradition. The debate remains and the floor is yours…

Christian R. Noe
and Daan J.A. Crommelin

New EUFEPS Executive Member

At Council, on September 20, 2008, in Ljubljana, Dr Sven Stegemann was elected new member of the EUFEPS Executive Committee.

Dr Stegemann graduated at the Free University of Berlin DE. After a job in public pharmacy, he joined the German Medicines Agency (Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM) in Bonn DE. Pharmacology was the domain for his PhD at the Universities of Frankfurt and Düsseldorf, Germany.

His pharmaceutical company career started with Sanofi-Winthrop, after which he joined Asta Medica, both in Germany. Since 2004, he is Director Global Pharmaceutical Business Development, Capsugel, Bornem BE.

Dr Stegemann is member of the EUFEPS Committee on Industrial Research Relations (CIRR), since 2001. His experiences also include the European Association of Pharma Biotechnology (EAPB), the Pharma Medicinal Biotechnology Section of the European Federation of Biotechnology (EFB), the Editorial Board of New Biotechnology and of numerous organising committees of scientific meetings, including for EUFEPS, EAPB, AAPS and APV.

EUFEPS in 2008:

The State of the Union

Now that 2008 is running near to its end, the time has come to 'reckon up the balance'. Was 2008 a good year for EUFEPS? Was 2008 an easy year for EUFEPS? Was 2008 a year for EUFEPS 'to forget as soon as you can'? One thing is clear: 2008 was full of dynamics; hardly a dull moment.

Organisation and finance

Therefore, this time first a topic that is usually dealt with somewhere at the end. It is: organisation and finances.

The changing economic climate (cooling down instead of heating up) called for immediate action and creative solutions to face a sudden financial headwind. The headquarters of EUFEPS in Stockholm was reorganized, and measures were taken to build a financially strong EUFEPS, in the years to come with an organisation that is 'lean and mean' and, above all, flexible. I would like to express my thanks to all of those who made this fast maneuvering possible. Coming from a country where biking is still a rather common form of transport: biking into a headwind makes you fit. I hope that also counts for EUFEPS.

In the last EUFEPS Newsletter (June-September 2008) Hans H. Linden, our CEO, described 'EUFEPS today'. A highly interesting, very informative contribution about EUFEPS: its organisation, its historical perspective and its activities. Highly recommended reading, in particular for those who just joined EUFEPS! I don't want to repeat what the EUFEPS' CEO already conveyed. I prefer to present some highlights, maybe with some bias. Forgive me …

Global interactions

In September 2008, EUFEPS became full member of the International Pharmaceutical Federation, FIP. It joined the group of science-driven FIP members, called PSMOs: Predominantly Scientific Member Organisations such as AAPS and the PSJ (Pharmaceutical Society of Japan).

The activities of a number of Networks of EUFEPS (see below) are partly run in parallel with the Special Interest Groups (SIG) of FIP, which gives easy access to a worldwide network of researchers. In the framework of the organisation of the 2009 PharmSciFair and the PSWC 2010 (Pharmaceutical Sciences World Conference) contacts were made to AAPS. The interactions with the Controlled Release Society (CRS) have not been intensified. EUFEPS maintained and built good relationships with the International Society for Pharmaceutical Engineers, ISPE, running joint workshops.

European interactions

In 2008, European Framework Projects were continued e.g. BioSim and concluded e.g. EUMAPP, which expired mid-2008. The annual meetings of the European Association of Faculties of Pharmacy (EAFP) were attended and presentations were given. The Pharmacogenomics network is actively seeking funds to run a European Drug Safety Biobank in the framework of the Innovative Medicines Initiative (IMI). EUFEPS played an active role in formulating Expressions of Interest for the first call of the Innovative Medicines Initiative (part of the 7th European Framework Programme).

In total, EUFEPS is fully involved in 3 out of the 5 topics of interest in Education and Training (on 'Safety Sciences for Medicines', on 'Pharmaceutical Medicine', and on 'Integrative Medicines Development'). The full IMI education and training proposals have to be finalised early in 2009 and actions will hopefully start without delay. EUFEPS took the initiative to visit to the leadership of the European Pharmacopoeia and the ESF (European Science Foundation) recently.

In addition, EUFEPS is engaging in a 7th European Framework Programme Application of MediCEMP (Medicines for Children European Microdosing Partnership), which is a follow-up and continuation of the 6th European Framework EUMAPP (European Union Microdose AMS Partnership Programme).

Steering Committee on Membership Development

The number of member organisations of EUFEPS has been rather stable over the years. EUFEPS' ambition is to reach out to those countries in (South) Eastern Europe where organisations are not yet members, and where there is a desire to join EUFEPS, but where the financial means are lacking. The Steering Committee on Membership Development started working out ideas on how increase the visibility of the 'new European countries' in EUFEPS. A first initiative to involve more Balkan countries >>>

in EUFEPS activities was taken and will be continued in 2009.

Steering Committee on Education and Training

The Committee on Training and Education (CTE) reconsidered its strategy, and is transforming itself into a Steering Committee on Education and Training. In the past, the committee tried to set up and run courses together with EUFEPS member organisations and other 'friendly' organisations and institutions. In the new strategy, the committee will act as a facilitator to initiate high quality educational activities in the pharmaceutical sciences in Europe. Committee members have been involved in the selected IMI education and training programmes and will continue this.

A special word should be included about the 'Vienna Branch Office' of EUFEPS. I normally don't use names in such a report. However, I would like to mention here the names of Professor Norbert Haider, leader of this Vienna Branch Office, which focuses on developing e-learning programmes in the pharmaceutical sciences for Europe and who is now stepping into the shoes of Dr Menno van de Waart, the long-time and highly dedicated secretary of the CTE, who resigns due to retirement by the end of this year. The Branch Office ran two highly successful e-learning workshops in Vienna and will continue to do so.

Last but not least: The EUFEPS Catalogue with PhD and PostDoc courses in 5 European countries was launched on the website of EUFEPS. May I invite you to use this catalogue, to promote its use and to expand it with course information from other countries in Europe?

Networks and Committee of Industrial Research Relations (CIRR)

Without doubt the activities of the EUFEPS Networks and the CIRR are critical to the success of EUFEPS. In 2008 the following networks were operational:

- Bioavailability and Biopharmaceutics (BABP)
- Process Analytical Technology Sciences (PAT)
- Pharmacogenetics and Pharmacogenomics Research (PGPG)
- Safety Sciences

A major activity of all these networks is to serve their clientele, either by the organisation of workshop or conferences, or by acting as the 'scientific voice' in strategic and political discussions at the European or even global level. Networks are flexible entities within EUFEPS. We can start them and suspend them at will. Additional Networks are now emerging, including one on "Environment and Pharmaceuticals" and one on "Quality of Medicines". In 2009, these new Networks may take shape further, e.g. by presenting themselves in the PharmSciFair in Nice or at the FIP congress in 2009 in Istanbul. Those of you, who might be interested in joining Network activities, contact the Network leadership via the EUFEPS website or secretariat. In principle, networks are open institutions.

The CIRR is a long-standing and active think-tank of EUFEPS, contributing a lot, over many years and 2008 was no exception!

The EUFEPS Senate of European Pharmaceutical Scientists

A major goal of EUFEPS is to further increase the quality of European pharmaceutical research. At the same time, it is critically important to make the pharmaceutical sciences more visible as one of the core areas of the life sciences with exciting perspectives and not as a mere conglomerate of various disciplines. Therefore, the already existing scientific community of pharmaceutical scientists has to be supported and care has to be taken that pharmaceutical competence and excellence are further advanced. The Executive Committee of EUFEPS has discussed this topic several times and has come to the conclusion that it would be extremely helpful to have a "sounding board" of top experts to support the activities of EUFEPS. It was decided that a EUFEPS Senate of European Pharmaceutical Scientists should be established. The first steps to implementation have been taken and we hope to have a fully (wo)manned Senate up and running in 2009.

Steering Committee for Meetings and Events

EUFEPS organised a number of workshops/courses or conferences in 2008:

- Optimising Biotech Medicines: Development of Safe Protein Therapeutics: Preclinical, Clinical and Regulatory Issues, March 10-11, 2008, Munich DE, co-organised with DPhG
- When Variability Becomes an Issue in Drug Development: How to Understand, Predict and Manage?, May 13-14, 2008, Verona IT
- (7th) High-throughput (HT) Drug Metabolism/Disposition (DM/D) Course, May 26-30, 2008, Amsterdam NL, co-organised with the Free University of Amsterdam and LACDR
- Monoclonal Antibodies: Cutting-edge Science for New Medicines, June 3-5, 2008, Heidelberg DE, co-organised with the European Association of Pharma Biotechnology (EAPB)
- Microdosing in Drug Development: Current Status and Future Perspectives, June 16, 2008, Bad Homburg DE, co-organised with EUMAPP
- New Regulations in Bioequivalence – Revised CHMP Note for Guidance, June 17-18, 2008, Bad Homburg DE
- Workshop – Hands-on Implementation of Process Analytical Technology (PAT) Systems in Production Processes, August 25-26, 2008, Ghent BE, co-organised with the PAT Group, Ghent University, Faculty of Pharmaceutical Sciences
- Workshop on Opportunities and Challenges in Vaccine Delivery, September 15-17, 2008, Site d'Archamps FR, co-organised with FIP
- The EuPAT3 Conference, October 7-8, 2008, Gothenburg SE, co-organised by ISPE Europe
- Conference on Drug Transport and Delivery: Impact on Drug Discovery and Development, October 8-10, 2008, Uppsala SE

Additionally, EUFEPS has co-sponsored several events with other organisations. All workshops and conferences are routinely evaluated. Quality-wise, participants judge these 'Meetings and Events' between very good to excellent. Unfortunately, for some of the above listed activities the number of participants was below expectations. EUFEPS staff and organisers did their utmost to minimise the loss.

The Pharmaceutical Sciences Fair - PharmSciFair

And then, … In 2009 the second PharmSciFair will be held in Nice, France. This premier event of the pharmaceutical sciences in Europe is, this time, supported by 40 organisations with a national or pan-European basis. EUFEPS incoming President, Pia Vuorela, and the EUFEPS' CEO, Hans H. Linden, together with a larger planning team, form the leadership of this in many aspects challenging event. May I call on you to promote this unique event wholeheartedly? This event should become THE place, where the European pharmaceutical scientists and leadership convene.

In closing

And that was your president's choice for the 'State of EUFEPS'. If I forgot something special: tell me and forgive me.

And to all European scientists, EUFEPS member or not: I wish you a happy, healthy and very productive 2009. Let's meet in June in Nice, the city where the Latin expression: 'Nomen est Omen' holds!

Daan JA Crommelin, Professor
President of EUFEPS

Spotlight on EPSA

Introduction

The European Pharmaceutical Students Association (EPSA) was founded in 1978. Since then, the association has grown and developed several important projects, which have secured EPSA an esteemed place amongst European Associations. The role of the pharmacist today is extremely wide ranging from community and hospital pharmacies to industry, cutting-edge research and the development of new cures for old diseases. EPSA is proud to represent the interests and beliefs of students within the pharmaceutical field, as students are the future workforce and also hold the future of this respected profession in their hands.

Organisation

EPSA is a non-profit organization representing 120,000 pharmacy students in 29 European countries. EPSA's Permanent Office is situated Brussels within the offices of the Pharmaceutical Group of the European Union (PGEU). Our aims are to develop the interests and opinions of European pharmacy students and to encourage contact and co-operation between them, to lobby for important topics on a European level, to promote mobility and create opportunities on an academic, social and professional level for our members.

EPSA organises 4 main events per year which bring students from all member organisations together for one week. Our biggest event is the Annual Congress, held in April; this will be held in Reims, France next time. This is then followed by the Autumn Assembly which is organised in collaboration with ESCP (European Society of Clinical Pharmacists) in October. EPSA also organises a Summer University and an Annual Reception each year.

The framework of the organisation includes 7 Working Committees involving more students on a local level to participate in EPSA projects, surveys, publications and events. Thus, we are reaching out to more of the potential future workforce of the pharmaceutical field worldwide. EPSA conducts studies in collaboration with local students in order to deliver information to professional bodies such as EAHP, ESCP, PGEU, and EIPG. Recent surveys created by the association targeted the students' knowledge and perception of Sexually Transmitted Diseases, E-learning & E-pharmacy, the Bologna Process, Pharmacovigilance and Pharmaceutical Care. This year we are working on a survey dealing with information to patients, which will be released in the coming months and promoted via our website, emails and local associations amongst others.

Individual Mobility Project

EPSA also has several ongoing official projects within the areas of mobility; education; humanitarian aid; lifelong learning; public health and pharmaceutical sciences amongst others. One of the newest , most important projects of EPSA is the IMP – Individual Mobility Project. This Project aims to give students and recent graduates from all European countries (members of EPSA) the opportunity to gain an additional real-time work and research experience in any field within the pharmaceutical profession. Additionally, the IMP represents an incomparable opportunity for participants of this project to gain valuable experience abroad thus producing a more socially mobile and diverse pharmaceutical work force. The IMP was created with four main objectives:

- To make research and practice (IMP training) more reachable for all European students of pharmacy
- To give European pharmacy students the opportunity to learn how to work in a foreign, challenging environment and also to gain experience and knowledge of working customs, different from those offered in their home country, necessary for development of their future career.
- To offer companies the most competent trainees with the best profile fitting their requirements and their needs, who might also become their future employees
- To interconnect research, work and procedures in the companies with the theoretical knowledge of students, who have the opportunity to implement their knowledge in such organisations.

This Project is a great programme which has all the potential to break down the European barriers and unify all European countries, especially with regard to exchange of pharmacy students or recent graduates, and later on also pharmacy professionals.

The EPSA IMP will also offer a great chance for networking between companies and other institutions (such as hospitals, research institutes, faculties of pharmacy) on all levels.

EPSA also publishes a newsletter three times a year, which is distributed together with other publications to the member faculties, partners, observers, honorary life members and individual members of EPSA.

Partners needed

EPSA requires the support of several partners to;
continue working effectively and developing projects further
to become more professional and offer member organisations the best opportunities to increase their experience
increase motivation ensuring that future pharmacists will continue to hold a praiseworthy function within the healthcare world.
Becoming an EPSA partner would give you the opportunity to develop a fruitful collaboration with our network of students, who will become a significant proportion of the future workforce of the pharmaceutical field worldwide. You could also attend EPSA events and talk to the students and access the data collected through our studies.
Please feel free to contact EPSA by writing to us at partners@epsa-online.org.

Marisabelle Bonnici
President, EPSA

Counterfeit Medicines in Europe

An early case

Counterfeit medicines have been with us in Europe since at least 1992. An Afro-Caribbean woman in The Hague, The Netherlands, asked her family doctor to write a prescription for a corticosteroid cream for skin bleaching purposes. The Dermovate® cream she had bought at her local tropical food store lacked efficacy. A sales representative of Glaxo bought a tube of Dermovate® cream. In the Glaxo laboratory no active substance was found. The tube, box and patient leaflet were all found to be counterfeit. [Image 1] The Dutch medicines inspectorate was notified and subsequently many thousands of corticosteroid creams were seized in all major Dutch cities. Similar cases were found in the United Kingdom. A network of illegal distributors was uncovered and traders were sentenced both in The Netherlands and in the UK.

More serious cases

The use of these medicines bought from illicit sources, including the internet, could be regarded as purely recreational. The term "life-style drugs" is sometimes used. In recent years a shift is observed from life-style drugs to life-saving medicines. Patients will not primarily buy these in illegal distribution. Regular distribution channels are therefore at risk of invasion by counterfeit medicines. This creates an increasing threat to healthcare systems throughout Europe. Indeed, already counterfeit medicines have appeared in pharmacies. In 2004 in the UK and The Netherlands Cialis® was found in pharmacies. Lipitor® was found in the UK in 2005 and 2006. In 2007 a major case involved large amounts of Plavix®, Zyprexa® and Casodex®. A Clinical Research Organisation raised the alarm when French Plavix® was to be used as a comparator in a clinical study - the tablets being prepared for use differed considerably in weight from the original tablets and counterfeits were suspected. [Image 2] Further analysis confirmed this and demonstrated insufficient amounts of active substances.

In response to this development, a Working Group of Enforcement Officers under the Heads of Medicines Agencies of the EU actively investigates cases of counterfeit medicines on a member state basis; cross-border through appropriate bi-lateral legal gateways; or through Europol. The group contributes to initiatives by the European Commission to improve legislation and enforcement practices to tackle pharmaceutical crime in the EU.

Detection and prevention

Counterfeit Dermovate® cream in 1992 was detected because a user told her physician about the apparent lack of effect; the Cialis® case in 2004 started with a patient complaining about tablets that crumbled when cut in half; in 2007 a UK parallel trader noticed differences in Plavix blister packs; a UK CRO found a deviation in the average weight of tablets Plavix® used as comparator drug in a study. In short, most known cases of counterfeit products that that have penetrated legal supply chains have come to light because the product showed a deficiency that was noted by the user or distributor. Pharmacists should be aware that patients are a valuable source of experience with medicines. Receptiveness to signals from users is probably the cheapest way of detecting any problems. The existing system of reporting adverse events should be adapted to accommodate signals related to quality suspicions.

We can not solely rely on detection measures to prevent counterfeit products from getting to the patient. Medicines legislation on European and national levels is built on the principle of prevention. No product shall come onto the market unless the efficacy and safety have been assessed by those qualified to do so in the respective licensing authorities. Once a product has been licensed, production and distribution is also well regulated. The examples of counterfeit medicines mentioned show that there is pressure on the system and that the presence of unreliable distributors cannot be ruled out. Pharmacists have the obligation to practice safe and secure business. Standards like GMP or GDP should be used, together with criteria related to due diligence around financial and ethical behaviour. This requires a near forensic approach to business dealings, which may come alien to modern day pharmacists but could significantly help combat unsafe, illegal medicines from getting to patients. To prevent any medicinal product that is unreliable from reaching the patient and to detect whenever a patient suffers unexplained side effects lies at the heart of the profession of the pharmacist. The relatively small number of cases whereby counterfeit medicines have been found in the regular distribution channels may be the tip of an iceberg. The volume of this iceberg can be estimated when more is known about the effects of these illegal medicines on the health of patients. In February 2009 the School of Pharmacy at Utrecht University in The Netherlands will organise a five week course on Forensic Pharmacy for Masters students. The aim of this project is to raise awareness with future healthcare professionals and to explore the potential of pharmaceutical sciences to uncover the hidden facts of counterfeit medicines.

Marcel Moester
Dutch Healthcare Inspectorate
The Netherlands

Image 1

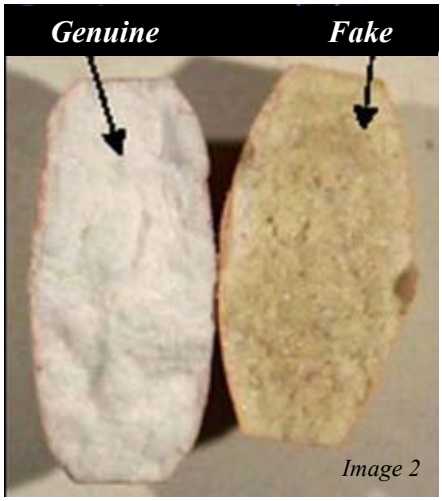


Image 2

Conference Report

7th Central European Symposium on Pharmaceutical Technology and Biodelivery Systems

September 18-20, 2008, Ljubljana

EUFEPS President, Prof. Daan J.A. Crommelin, speaks at the Symposium Banquet. Those behind him are, from the left: Ales Mrhar, and EUFEPS Executive Committee Members Pia Vuorela, Christian R. Noe, Buket Aksu and Hans H. Linden.

Introduction

The 7th Central European Symposium on Pharmaceutical Technology and Biodelivery Systems was organised by the Slovenian Pharmaceutical Association and the Faculty of Pharmacy, University of Ljubljana. The event took place in Ljubljana, Slovenia, from 18th to 20th September. The preparations started in 2006 and, during this period of time, contacts with 14 European pharmaceutical associations including Austria, Bosnia and Herzegovina, Czech Republic, France, Croatia, Italy, Hungary, Macedonia, Germany, Poland, Slovak Republic, Serbia, and the European Federation of Pharmaceutical Sciences (EUFEPS) as the main patron association were established. With the help of these associations, the event became more visible spreading the information about the symposium among different international experts and scientific environments.

Symposia and lectures

The symposium consisted of two parts. The first part included a satellite symposium entitled: ***Challenges and opportunities in multiparticulate drug delivery***. Here five top lecturers from abroad and three national lecturers participated in the programme. The second part was the main event, in which 7 different sections were scheduled over the next two days. The plenary lectures were presented by acknowledged European scientists. There were oral presentations, which were selected among the accepted abstracts by an internationally composed scientific committee, and posters.

The objective of the main symposium and the satellite symposium was to enable the exchange the knowledge and ideas among the scientists and experts from different areas of interest and different fields: regulatory authorities, academic institutions and R&D divisions of pharmaceutical companies. Extended abstracts were received from the participants within three groups of topics: drug delivery systems, pharmaceutical operations and processes, and biopharmaceutical evaluation of both active substances and medicines.

Focus on delivery systems

Delivery systems were embraced into this symposium in their widest scope; from introduction of excipients, according to their functionality, to their implementation into new pharmaceutical forms or new technological processes. Moreover, the physico-chemical characterisation of excipients in connection with their efficacy and safety in vivo were fully presented. The main part of the lectures and presented posters originated in the development of macro-, micro- and nano-delivery systems, all being the hottest topics in modern pharmaceutical technology. Furthermore, new possibilities, applicable in industry, were introduced for incorporating poorly soluble small molecules of chemical origin and newly developed biopharmaceuticals into drug delivery systems. The use of stem cells was presented in the treatment of Alzheimer's disease. Additionally, different experimental models *(in vitro, ex vivo, in vivo, in silico)* for the study of mechanisms and kinetics of LADME processes (**L**iberation, **A**bsorption, **D**istribution, **M**etabolism, **E**limination) were critically evaluated and directions for their further development were proposed.

Excellent attendance

This symposium exceeded our expectations in many ways. More than 280 experts from 21 countries from all five continents participated the symposium. There were 6 plenary lectures, 7 invited lectures, 25 short oral presentations and 157 posters presentations. During the symposium there was an exhibition with different pharmaceutical companies, which presented novelties in technological equipment, analytical methods, and new materials.

An additional contribution to the symposium was given by the meeting of the Council and the Executive Committee of EUFEPS, which ran in parallel with our symposium. Consequently, the President of EUFEPS, Prof. Daan J.A. Crommelin was among our distinguished guests.

On the basis of participants' feedbacks and their good responses on the outcomes of the symposium, we can conclude that our objective was reached. The contents of the main and satellite symposium showed the solution of some challenges in modern pharmaceutical development. At the same time many questions remained unanswered. However, some unsolved problems that remain will lead to further, even more intensive and more exciting research.

Publication of key information

One of the most important results of this symposium is the publication of a special number of Farmacevtski vestnik (Slovenian Pharmaceutical Journal) consisting of extended abstracts of all presented works. Additionally, the editor of the International Journal of Pharmaceutics, Prof. A.T. Florence, who also participated in the symposium, offered us a special issue of this journal, which will consist of most acknowledged presentations. This special issue is entitled **Challenges in Nano- Micro- and Macro-systems** and is edited by **Prof. Aleš Mrhar** and **Dr. Saša Baumgartner.**

Prof. Aleš Mrhar, President of the Symposium

Dr. Saša Baumgartner, General Secretary of the Symposium

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

2009 2nd PHARMSCIFAIR

Premier European Platform for Advancing Pharmaceutical Sciences

June 8-12 • 2009 • Nice • France

Invitation to PharmSciFair 2009

Premier European Platform for Advancing Pharmaceutical Sciences

June 8 – 12, 2009, Nice, France

Dear Colleagues,

It is a pleasure for us, the Planning Team, to invite you all to the 2nd Pharmaceutical Sciences Fair and Exhibition in Nice, France, which is an excellent location. We wish to assure you that it will be a very important meeting, as a broad partner representation of 40 different national and international organisations and networks has actively contributed to putting the appealing scientific programme together. In addition to the expanded programme, compared to the 1st PharmSciFair in 2005, there is a Careers Forum and a Pre-Satellite Young Scientists Meeting. The 2009 PharmSciFair is a collective undertaking at all levels.

We are convinced of the need to carry the pharmaceutical sciences forward in both formal and informal settings, enabling all partners to think and consult together and to share experiences. PharmSciFair is to be understood as a mechanism for scientific deliveries, which will allow us to understand the different approaches, perspectives and sensitivities among the different players represented by people from academia, industry and regulatory. Building on the strengths of each and every actor, it will ensure a consolidated movement towards common goals and targets. PharmSciFair will create synergy within the array of different disciplines.

At the Opening Session, a prestigious group of influential leaders will contribute to a common vision of pharmaceutical sciences, in both the short and the long term. Pharmaceutical science as a multi-faceted concept is reflected in the programme of this event, which is wide-ranging in terms of content, activities and participating partners.

Therefore, we urge you all to participate in the 2009 PharmSciFair and to invite your colleagues to do so as well!

Pia Vuorela, Professor
Chair 2009 PharmSciFair

EUFEPS BABP Network Open Discussion Forum: Revised European Guideline on Bioequivalence

January 14-15 • 2009 • Bonn • Germany
First day 9:15 am to second day 4:30 pm

The basis for this meeting is the draft for the revised version of the CPMP Note for Guidance on the investigation of bioavailability and bioequivalence, released for consultation in July 2008 (www.emea.europa.eu/pdfs/human/qwp/140198enrev1.pdf).

Discussion topics, amongst others, will be:

- proposed regulations on characterisation of the investigational medical product (IMP)
- administration conditions (single dose fasted as "gold standard"?)
- alternative designs (e.g. two stage studies)
- exclusion of subjects
- measurement of metabolites and enantiomers
- bioanalytical procedures
- dose strengths to be studied
- studies on special dosage forms
- PK parameters and acceptance criteria
- highly variable drugs
- urinary data
- statistical procedures
- dissolution tests
- BCS-based biowaivers

Discussions will be based on comments submitted to the organisers in the run-up phase to the event. All participants are invited to present their views and suggestions, based on their own experience, during the discussion, and to support these proposals with experimental data.

More information, registration form and accommodation etc. is available on the EUFEPS Online (www.eufeps.org), including as pdf. Alternatively, contact the EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Tel +46 8 7235000, Fax +46 8 4113217. Email conferences@eufeps.org

Networking in Pharmaceutical Sciences

Friday • February 27 • 2009 • Zagreb • Croatia
9 am to 4:30 pm plus Dinner

There is a need to further encourage and boost biomedical research across Europe.

Researchers in the field include scientists in drug modelling and simulation, medicinal chemistry, pharmacogenetics and genomics, systems approaches, gene therapy, pharmacology, pharmacokinetics, drug metabolism, toxicology, pharmaceutical formulation, drug delivery, pharmaceutical physico-chemistry, new *in-vitro/in-vivo* models, safety sciences, and so forth … as well as decision-makers at all levels. All should be there. The Conference will open at 9 am, and it will close at 4:30 pm. In addition, there will be a dinner at 7 pm.

Organisers of this conference are the Croatian Pharmaceutical Society (CPhS) and the European federation for Pharmaceutical Sciences (EUFEPS). It is co-sponsored by the Croatian Agency for Medicinal Products and Medical Devices (ALMP), and the Croatian Association of Research–Based Pharmaceutical Companies (CARPC) - Associated Member of the European Federation of Pharmaceutical Industries and Associations (EFPIA)

Download the Conference Programme, Accommodation and Registration Information etc. from e.g. the EUFEPS Online Current Meetings (www.eufeps.org), or contact Milena Jadrijević-Mladar Takač, Faculty of Pharmacy and Biochemistry, University of Zagreb; Email mladar@pharma.hr; Tel +385 1 4828192.

Bottlenecks Identification in Drug Discovery... And Solutions Please!

January 22 • 2009 • Leiden • The Netherlands
9 am to 5 pm

We all know that the pipeline of new molecular entities for the treatment of diseases is at a record low, in spite of large financial investments and revolutionary discoveries in basic science. Both the EMEA 'Roadmap to 2010' and the FDA 'Innovation or Stagnation' report analyse this situation and suggest adjustments to the current paradigm. What are the bottlenecks in the discovery phase of new drugs and what are possible solutions to improve performance? These questions must attract those who care about pharmaceutical sciences and their translation into medicine.

For participants resident or working in the Netherlands will have free admission. For all others there is a registration fee.

Organisers of this conference are the Dutch Top Institute Pharma and the European Federation for Pharmaceutical Sciences.

Detailed information is available at: www.tipharma.com/pro1/general/home.asp or at: http://www.eufeps.org/ Alternatively, contact the EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Tel +46 8 7235000, Fax +46 8 4113217. Email conferences@eufeps.org

8th Training Course on High-throughput (HT) Drug Metabolism/Disposition (DM/D)

May 25 - 29 • 2009 • Amsterdam • The Netherlands
First day 9 am to fifth day 3:30 pm

This course comprises theoretical and practice-oriented training in drug metabolism, disposition and safety, with special emphasis on modern high-throughput aspects – maximum 25 participants.

Specific goals

- To learn to critically evaluate the basic concepts of HT technologies in drug metabolism/disposition
- To learn the possibilities but also the limitations of HT-drug metabolism/disposition technologies in daily practices
- To stimulate interdisciplinary learning of HT drug metabolism/disposition
- To stimulate research in and applications of HT drug metabolism/disposition
- To prepare new industrial and academic recruits better to meet the challenges of HT technologies in drug metabolism/disposition

Those to attend

- Post-doctoral/advanced PhD (or equal) level attendees from industry, CROs and innovative equipment and instrument manufacturers, as well as from academia
- Those working in pharmaceutical, bio-technological, bio-analytical, agro/fine chemical fields and in (bio)informatics

Course Leaders

Nico P.E.Vermeulen and Jan N.M.Commandeur, Amsterdam NL

Additional Information

For more information, registration form and accommodation etc., consult the Course Website (www.chem.vu.nl/en/sec/far/HT-DMD_course), the EUFEPS Online Training and Education Section (www.eufeps.org). Alternatively, contact the EUFEPS Secretariat, PO Box 1136, SE-111 81 Stockholm, Sweden. Tel +46 8 7235000, Fax +46 8 4113217. Email conferences@eufeps.org

European Guidelines on Bioequivalence
January 14-15, 2009, Bonn, Germany
Contact: EUFEPS Secretariat, PO Box 1136
SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org
ww.eufeps.org

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Bottlenecks identification in drug discovery... And solutions please!
January 22, 2009, Leiden, The Netherlands
Contact: Top Institute Pharma
www.tipharma.com/pro1/general/home.asp or
EUFEPS www.eufeps.org

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Advanced Techniques in Synthetic Organic Chemistry
January 5-16, 2009, Copenhagen, Denmark
Mass Spectrometry Coupled to Separation Techniques in Bioanalytical Chemistry
January 19-23, 2009, Copenhagen, Denmark
Molecular Pharmacology
January 19-23, 2009, Copenhagen, Denmark
Hands-on Reference Manager
January 27, 2009 (afternoon), Copenhagen, DK
Biostructures and Molecular Modeling in Drug Research
February 2-13, 2009, Copenhagen, Denmark
Journal Club in Biopharmaceutics, Pharmacotherapy and Pharmacoepidemiology
February 3, February 17, March 3, Mach 17, March 31, April 14, April 28, May 19, 2009, Copenhagen, Denmark
Drug Design and Discovery
March 2-6, 2009, Copenhagen, Denmark
Pharmacokinetics – Pharmacodynamics
March 9-13, 2009 (preliminary dates), Copenhagen, Denmark
Contact: The Faculty of Pharmaceutical Sciences, University of Copenhagen, 2 Universitetsparken, DK-2100 Copenhagen Denmark, Email master@farma.ku.dk
www.farma.ku.dk/postgrad-courses

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The Critical Path and Innovative Medicines Initiative
February 11, 2009, London, UK
Contact: Society of Pharmaceutical Medicines Secretariat, 9 Red Lion Court
London EC4A 3EF, Fax +44 020 79365901
Email v.wood@iob.org , www.socpharmed.org

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logP2009, PhysChem and ADMET Profiling in Drug Research. The 4th LogP Symposium
February 8-11, 2009, Zürich, Switzerland
Contact: Email info-LogP2009@pharma.ethz.ch
www.LogP2009.ethz.ch

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Networking in Pharmaceutical Sciences
February 27, 2009, Zagreb, Croatia
Contact: Milena Jadrijevic-Mladar Takac
University of Zagreb
Email mladar@pharma.hr , www.eufeps.org

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Formulating Better Medicines for Children
March 2-3, 2009, London
Traditional herbal medicines: opportunities and challenges in a changing regulatory environment
March 6, 2009
The Development of Veterinary Medicines
April 27, 2009, London, UK
Contact: Gabriella Highfield, Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street, London SE1 7JN, UK
Fax +44 20 7572 2506
Email gabriella.highfield@rpsgb.org
www.jpag.org

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Training Course: Development of Biopharmaceuticals as Innovative Drugs
March 2-5, 2009, Leiden, The Netherlands
Contact: LACDR Office, Leiden University
Gorlaeus Laboratories, P O Box 9502, NL-2300
RA Leiden, Fax +31 71 527 4277
Email e.devries@lacdr.leidenuniv.nl
www.brpl.nl

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Clinical trials directive – five years on
March 5, 2009, London, UK
Travel Medicine – moving practice forward
March 12, 2009, London, UK
Impact of ICH Q8, Q9 and Q10: fact or fiction?
April 23, 2009, London, UK
Contact: Secretariat, Ms Julie Churchill
3rd floor, RPSGB, 1 Lambeth High Street,
London Se1 7JN, UK, Fax +44 20 7572 2506
Email science@rpsgb.org , www.jpag.org

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DUPHAT 2009
Dubai International Pharmaceuticals and Technologies Conference and Exhibition
March 29-31, 2009, Dubai, UAE
Contact: INDEX®Conferences & Exhibitions Organisation Est
Phone: +971 4 3624717
Email: duphat@index.ae

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Meeting on Nanotechnology, Liposomes and Health
April 17-20, 2009, Bahia, Brazil
Contact: Swedish Academy of Pharmaceutical
http://sec.adtevento.com.br/liposome/site/

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The 2nd International Meeting on NMR and Quantitative Analysis
April 21-22, 2009, Stockholm, Sweden
Contact: Swedish Academy of Pharmaceutical Sciences, Att. Jenny Hagberg, P O Box 1136
SE-111 81 Stockholm, Sweden
Fax +46 8 149820
Email jenny.hagberg@lakemedelsakademin.se
www.lakemedelsakademin.se/NMR2009

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Hands-on Workshops on Concepts & Applications of Population-based In Vitro-In Vivo Extrapolation of ADME Properties
April 27-May 1, 2009, Washington DC, USA
May 25-29, 2009, Leiden, The Netherlands
Contact: Simcyp Ltd, Att. Kelly Jinkinson, Blades Enterprise Center, John Street, Sheffield S2 4SU, UK, Fax +44 114 2922333
Email workshops@simcyp.com
www.simcyp.com

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Qualitative and Quantitative Research Methods in Pharmacy Practice and Medicine Use
May 11-15, 2009, Copenhagen, Denmark
Receptor Structure and Function
May 11-15, 2009, Copenhagen, Denmark
Drug Delivery
May 25-29, 2009, Copenhagen, Denmark
Contact: The Faculty of Pharmaceutical Sciences, University of Copenhagen
2 Universitetsparken, DK-2100 Copenhagen
Denmark, Email master@farma.ku.dk
www.farma.ku.dk/postgrad-courses

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In vitro Toxicology Testing Methods
May 12-14, 2009, Stockholm, Sweden
Contact: Viktoria Axelsson or Erica Toft
Email forinvitox@expertradet.se
Email erica.toft@silverdal.se

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High-throughput (HT) Drug Metabolism/ Disposition Course
May 25 - 29, 2009, Amsterdam, The Netherlands
Contact: EUFEPS Secretariat, PO Box 1136
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Email conferences@eufeps , www.eufeps.org

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PharmSciFair
June 8-12, 2009, Nice, France
Contact: EUFEPS Secretariat, PO Box 1136
SE-111 81 Stockholm, Sweden
Email conferences@eufeps.org , www.eufeps.org

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New Website Layout for EJPS

At the beginning of December 2008, there have been dramatic improvements in the appearance of the website for the European Journal of Pharmaceutical Sciences, the official journal of EUFEPS.

Please take a look at http://www.elsevier.com/wps/find/journaldescription.cws_home/523997/description#description
Or follow the links from EUFEPS Online www.eufeps.org