IFAPP WORLD
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International Federation of Associations of Pharmaceutical Physicians
I·2006·JULY

CONTENT

President's Letter

Dear Colleagues

I am pleased to announce the re-launch of IFAPP World, which will now be published three times a year. We recently asked our member associations how IFAPP could better serve their needs. While the full results of the questionnaire will be published in the next edition, two key requests were for a digest of member events and international news of relevance to pharmaceutical medicine. Please submit articles and news of your local associations to our managing editor, Eckhard Boettcher-Buehler (his email is boebue@t-online.de). The content box to the left of this article describes the key themes of this inaugural issue.

During my term I have seen continuing progress towards wider recognition of pharmaceutical medicine as a medical specialty, helped considerably by the activities of the CEPM in harmonizing the content of postgraduate courses.

IFAPP continues to collaborate actively with regulatory agencies and the EACPT. Two successful EMEA-IFAPP meetings took place, while both FDA and EMEA staff ▶ page 2

Questions & Answers

Beyond the Horizon

"See you at ICPM 2006 in Seoul, Korea"

In preparation for the 14th International Conference on Pharmaceutical Medicine (ICPM) in Seoul, Korea, September 3-6, 2006, Eckhard Boettcher-Buehler from IFAPP WORLD had a brief conversation with Dr Yil-Seob Lee, chairperson of the ICPM Organizing Committee.

Dr Yil-Seob Lee, chairperson of the ICPM Organizing Committee, in dialogue with IFAPP WORLD.

IFAPP WORLD: Dr Lee, the 14th International Conference on Pharmaceutical Medicine will be the first ICPM held in the Asia Pacific region – is this Beyond the Horizon, or a new hot spot for pharmaceutical medicine?

Dr Lee: The theme "Beyond the Horizon" works several ways. As Pharmaceutical Medicine is a new area of medicine in Asia, we would like to open this new area to Asian people and also introduce Asian pharmaceutical medicine to western people. Another point is that the Asian pharmaceutical market has gained considerable attention recently from multinational companies. Apart from the region's size, which translates to a wide consumer base, Asia has become an important site for clinical trials and has achieved excellence in the field of research and development. ▶ page 2

News from IFAPP's CEPM

CEPM's Initiative is Gaining Momentum

IFAPP's Council for Education in Pharmaceutical Medicine (CEPM) recently set up a series of Working Groups (WG) with well-defined tasks as listed below. This CEPM initiative was designed to enhance development and continuing progress of the worldwide promotion of Pharmaceutical Medicine as a distinct specialty grounded in a body of knowledge, skills and attitudes acquired through harmonized education, training and practice. Indeed, this process is gaining strong momentum. The CEPM has visited, evaluated and accredited several Postgraduate Courses in Pharmaceutical Medicine in various regions worldwide. Full details concerning these courses can be found on IFAPP's website at www.ifapp.org in the menu section "education" subsection "courses".

CEPM Working Groups

• *WG on Guidelines for CME/CPD in pharmaceutical medicine* • This WG prepared a document to assist national member associations intending to set up a CME/CPD program for their members. The "CEPM Guidance Notes for the establishment of Structured National CME/CPD Programs for ▶ page 2

President's Letter

Dear Colleagues

spoke at an IFAPP symposium at the American Academy meeting.

IFAPP will shortly register as a non-profit organization in the Netherlands with a revised constitution, subject to ratification by the IFAPP Executive Committee and the House of Delegates at ICPM 2006. I urge you all to attend this meeting in Seoul, which gives us a unique opportunity to establish pharmaceutical medicine along the Asian rim. This issue includes an interview with Dr Yil-Seob Lee, the Chairperson of the ICPM 2006 Organizing Committee.

We now have a new vision for IFAPP: „by 2011, IFAPP is recognized and accepted as an authoritative voice on the medical aspects of the pharmaceutical industry and education and standards within pharmaceutical medicine by governmental and regulatory authorities, pharmaceutical industry bodies, the public, healthcare providers, healthcare professionals, academic and professional bodies and the media". The Executive Committee has committed to developing the strategy to implementing this vision, and needs your help to make it happen!

Finally, as the retiring President, I would like to thank the Executive Committee for their dedication and support over the past two years. I congratulate Dr Luis Collia on becoming the next President, and wish him all success in his future endeavors.

Dr Christopher Allen, IFAPP President

Questions & Answers

Beyond the Horizon

IFAPP WORLD: You call your country "Dynamic Korea" rather than "The Land of Morning Calm," its old nickname. How does this reflect its role in pharmaceutical medicine?

Dr Lee: Dynamism means full of energy and new ideas, which is exactly what characterizes the Korean pharmaceutical industry. The Korean pharmaceutical market – the 11th largest market in the world – is changing. Korean pharmaceutical companies in the past concentrated on the local market, but now have started to look outside their physical border, gaining interest in the international markets and bring innovations by being involved in ambitious research and development. Along with these changes, Korean pharmaceutical medicine is developing rapidly and dynamically. More physicians are working within the pharmaceutical industry in various areas.

IFAPP WORLD: Inevitably we have to touch on this: Considering Korea's Woo-Suk Hwang, his stem cell research and its subsequent disaster are infamous around the world. Did this unfortunate incident alter Korea's image and perception of expertise as a top researching country?

Dr Lee: I would say that this sad episode has to some extent tarnished Korea's image in the field of research, although this is more of an isolated case than a prevailing practice. However the good news is that the Korean government's impartial handling of this case shows to the whole world that we acknowledge the seriousness of this case and does not and will not tolerate such acts again in order to restore ethical standards that might have been shattered. Maybe this incident should very well serve as a reminder to all researchers how important the ethics of research is.

IFAPP WORLD: Beyond Korea's geographical horizon is China – dynamic as well and huge. Isn't that challenging for Korea?

Dr Lee: Surely, the emergence of China as a major economic power has piqued the interest of both media and investors. China has potential, but it will take time for its potential to be translated into reality. According to a survey by the Center for Medicines Research International, which was featured in Applied Clinical Trials, although China will become a country of great commercial importance, Korea is going to be an important market and it will retain a high market ranking for a long time. I think Korea will retain competitiveness in high-end research and in early stage of development. Throughout history, Korea has kept its own distinctive culture despite pressures from China and Japan, therefore Korea will also keep competitiveness in research & development in the face of similar pressures.

IFAPP WORLD: Last but not least: What should ICPM attendees expect in Korea's capital Seoul?

Dr Lee: From this meeting attendees can get updated knowledge on current research and development in pharmaceutical medicine and can learn how to collaborate with emerging countries.

Coming to Korea will give experience of 'beyond the horizon' in culture, atmosphere, food and people. Please come and enjoy it!

IFAPP WORLD: Thank you.

ICPM 2006 program details you find at page 10 to 13 in this IFAPP World issue or on the ICPM 2006 website at www.icpm2006.org.

News from IFAPP's CEPM

CEPM's Initiative is Gaining Momentum

Pharmaceutical Physicians" (see below) represents a significant step towards harmonizing the CME/CPD requirements in Pharmaceutical Medicine. Additionally it is an important advance in gaining widespread endorsement of this discipline as a separate medical specialty.

• *WG on the IFAPP syllabus* • This WG is focused on keeping IFAPP's syllabus current, reflecting the progress of science and knowledge in Pharmaceutical Medicine. The WG has developed an updated version of the syllabus taking into account input from all national member associations. This document is under evaluation by IFAPP's CEPM Board and will be sent to IFAPP's national member associations for adoption by their local post-graduate training courses.

• *WG on training of investigators* • This group screened available training courses for investigators. It selected one course as a basis for the production of a computerized interactive training course for investigators, which could be recommended by IFAPP for use all over the world. The WG is active in producing a final version of the course in collaboration with the vendor.

• *WG on a multilingual glossary* • The WG is working on a multilingual glossary of terms relating to clinical research and Pharmaceutical Medicine.

Gyeongbokgung Palace – Gyeongbok means Shining Happiness. Its main gate opens to one of the busiest areas of Seoul (KNTO).

News from IFAPP's CEPM

CEPM Guidance Notes: Setting Up National Education for Pharmaceutical Physicians

IFAPP's Council for Education in Pharmaceutical Medicine (CEPM) recently presented the *CEPM Guidance Notes for the establishment of Structured National CME/CPD Programs for pharmaceutical physicians* (February 17, 2006), prepared by a CEPM ad-hoc Working Group.

"The objective of this initiative is to aid IFAPP's national member associations in setting up their own CME/CPD schemes to improve the training and education of their pharmaceutical physician membership," CEPM Chairman Dr Juan Lahuerta said in his introductory letter. "This will promote the status of Pharmaceutical Medicine practitioners on an equal footing as the rest of medical specialists already complying with CME/CPD. Moreover, adopting a common approach would help in the harmonization of professional requirements in Pharmaceutical Medicine worldwide, thus facilitating the movement of pharmaceutical physicians between countries."

This idea is stressed even more vigorously in the introduction of the CEPM Guidance Notes; "Pharmaceutical physicians have a duty to keep their knowledge and skills up to date throughout their professional career in order to remain competent in the fulfilling of their multidisciplinary tasks."

Continuing Medical Education (CME) and Continuing Professional Development (CPD) are excellent instruments to help physicians remain current with scientific advances in general medicine and in medical specialties in particular – including Pharmaceutical Medicine. CPD programs also enable the development of new skills for maintaining and bringing professional practice to the highest possible standard.

Some European countries already have structured CME/CPD programs in operation for Pharmaceutical Medicine, but most countries in Europe and on the other continents are still in the organizational or planning phases. In order to assist IFAPP's National Member Associations in setting up their own local system and to ensure that these upcoming local CME/CPD programs will be harmonized between each other, the Working Group on CME/CPD of the IFAPP's CEPM has developed the current Guidance Notes.

The CEPM Guidance Notes for the establishment of Structured National CME/CPD Programs for pharmaceutical physicians are available on IFAPP's website at www.ifapp.org in the section "education" subsection "about CEPM."

A description of IFAPP's CEPM and its initiatives, a directory of Postgraduate Courses in Pharmaceutical Medicine in Europe and details on IFAPP's CEMP activities in accrediting Postgraduate Courses in Pharmaceutical Medicine also are available on IFAPP's website at www.ifapp.org in the menu section "education." ■

Personal Snapshot

Dr Herman Lahon, Brussels, Belgium, founding President of the IFAPP in 1975, IFAPP's Treasurer

Honorary Life President of IFAPP

Herman Lahon, a diligent worker, keen thinker and smart diplomat has throughout his career had the ability to focus on targets, create prolific working atmospheres, and to assist people and teams to reach decisions by consensus. He became the founding President of the IFAPP in 1975 and since that time he has been the Belgian Association of Pharmaceutical Physicians (BeAPP) Delegate on IFAPP's Executive Committee and House of Delegates. In his honor, in September 2004 he was elected as the Honorary Life President of the IFAPP. Congratulations.

When asked what he regards as the greatest challenge facing IFAPP in the future, he answered: "IFAPP's visibility and influence in the pharmaceutical world and among the medical profession still needs to be improved further in order to enforce worldwide recognition of pharmaceutical medicine as a new medical specialty. To achieve this, IFAPP continues to offer support to national member associations to set up continued and structured ▶ page 4

IFAPP's Calendar

Why Don't You Join BIO KOREA 2006 Right After ICPM?

Only 10 minutes away from Sheraton Grande Walkerhill Hotel, the venue of ICPM 2006 at September 3-6, 2006, is where BIO KOREA 2006 Conference and Exhibition is held from September 6-8, 2006 at the COEX InterContinental Seoul. As the first-of-its-kind international bio event in Korea, BIO KOREA 2006 will bring together more than 600 bio companies and regional bio clusters and bio centers that wish to build up business networks, investor relation & partnering as well as participate in the conference.

Do not miss this opportunity and check the benefits the organizers offer only to ICPM participants:

INCENTIVES	
Accommodation	2 complimentary nights at deluxe hotel near the venue
Exhibition	Free entry
Partnering	Free participation
Conference	50% discount for pre-registration
Welcoming Reception	Invitation card
Others	Shuttle service Walkerhill-COEX (10 min.)

To enjoy these incentives, participant registration should be made no later than August 4, 2006. For further details and updated information regarding BIO KOREA 2006, please visit its homepage at www.biokorea.org. If you have any inquiries about BIO KOREA 2006, please contact directly to BIO KOREA 2006 organizer's office by email (biokorea@kita.net), fax (+82-2-6000-5823/4), or phone (+82-2-6000-5118). BIO KOREA 2006 is waiting for you where you will discover new businesses and markets. Make your stay more meaningful and beneficial by joining ICPM 2006 and BIO KOREA 2006. ■

Personal Snapshot

Honorary Life President of IFAPP

◀ education in pharmaceutical medicine for physicians in their respective countries."

Pharmaceutical medicine indeed has its specific scientific, medical and regulatory fields, which distinguish its expertise from those of other clinical medical specialties. Herman Lahon is a key driver in harmonizing requirements for education in pharmaceutical medicine, devoting much of his time, effort and expertise to establish academic postgraduate education, peer and academic supervision, structured CME/CPD programs and awarding a specialist title. He hopes that through these structures, which today exist in only a few European countries, pharmaceutical medicine harmonization will develop all over the world assisted by the IFAPP, pharmaceutical physicians national associations and academic institutions.

"I am rather impatient when important issues are concerned," he admits. However, colleagues and friends describe him as a positive thinking man who always sees the glass half-full rather than half-empty. He is optimistic that international recognition of pharmaceutical medicine as a new medical specialty will progressively increase. "It is a slow process but some day it truly will be recognized like cardiology or nephrology."

In Brief:

Herman Lahon graduated as a Medical Doctor from the University of Brussels (ULB), Belgium, in the 1950's specializing in anesthesiology, tropical and pharmaceutical medicine. Immediately after graduation he spent six years as a medical practitioner and researcher in the Congo at the institute for improvement of nutrition in central Africa. In the 1960's he returned to Europe to accept a position in the pharmaceutical industry, the Belgian subsidiary of Pfizer, where later he was promoted to Vice-President Medical Director Pfizer Europe. In the mid-1980's he changed his position and became Medical Director for Rhone-Poulenc and moved on to the Headquarters of UCB as Director of Development and later as Global Medical Director UCB.

In addition to his assignments for IFAPP, he took an active part in the Faculty of Pharmaceutical Medicine in London. Founded in 1989, it soon counted more members from the world's five continents than from Great-Britain He was asked to represent the interests of non-British physicians on the Board of this Faculty. Later on he set up the Overseas Committee, then re-named the International Committee, chaired it until 2003, and still is its Deputy Chairman. As founding President of the BeAPP and a senior member of the Belgian College of Pharmaceutical Medicine he was instrumental in the set-up of the Postgraduate Courses in Pharmacology and Pharmaceutical Medicine at the University of Brussels (ULB). He also became founding chair of the IFAPP Council for Education in Pharmaceutical Medicine (CEPM*).

"If I could start again, which I would love to do, I would only change minor details. „For instance, several times I have been offered positions at Pfizer's Headquarters in New York, but I always turned them down. Restarting I would accept and go just to know whether I took the right decision to stay in Europe." However, looking back, he admits, "Do you know a better place than Brussels and a better time than the golden 1960's, 1970's, 1980's…?"

Eckhard Boettcher-Buehler

**For further information on IFAPP's CEPM please enter www.ifapp.org following "education" at the menu.* ■

Stay Tuned

U.S. Food and Drug Administration

Campaign to Reduce Medication Mistakes Caused by Unclear Medical Abbreviations

June 2006 • The U.S. Food and Drug Administration (FDA) and the U.S. Institute for Safe Medication Practices (ISMP) launched a nationwide health professional education campaign aimed at reducing the number of common but preventable sources of medication mix-ups and mistakes caused by the use of unclear medical abbreviations.

According to the U.S. Institute of Medicine (IOM) of the National Academies, there are more than 7,000 deaths a year due to medication errors. Mistakes can occur anywhere in the medication-use system, from prescribing to administering a drug in a variety of settings (hospitals, outpatient clinics, nursing homes, home care, etc.). A common error-prone notation includes the abbreviation IU for "international unit", which often is mistaken for IV (intravenous, intravenously).

"We recommend that ISMP's list of abbreviations, symbols and dose designations (see www.ismp.org/PDF/ErrorProne.pdf) most often associated with medication errors be considered whenever medical information is communicated," said Michael Cohen, ISMP President. The campaign materials also promote a brochure to be distributed to medical professionals, the pharmaceutical industry and medical publishing professionals, available on the Web at www.fda.gov/cder/drug/MedErrors and www.ismp.org/tools/abbreviations.

FDA/IFAPP ■

Stay Tuned

European Commission, European Medicines Agency, U.S. Food and Drug Administration

Cooperation on Medicines Regulation Intensified

March 2006 • The EU-FDA confidentiality arrangement was reviewed at a meeting of the European Commission, the European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA).

Following positive feedback from both regulators and industry that parallel scientific advice can facilitate the development of safe and effective medicines, it was agreed to extend the pilot phase for this process. Another area of particular benefit is pharmacovigilance, where close collaboration on a number of important issues has enhanced patient safety.

According to a joint press release this review resulted in an agreement to intensify transatlantic cooperation in the area of medicinal products, with particular focus on vaccines (including preparedness for influenza pandemic), medicines for children, medicines for rare diseases ('orphans'), oncology and pharmacogenomics. Other public health priority areas will be explored in the coming months, such as counterfeit drugs.

The arrangement has strengthened interactions between the regulatory authorities and contributed to improving the promotion and protection of public health.

EC/EMEA/FDA/IFAPP ■

▼

Reports & Concepts

8th EMEA-IFAPP Conference
London in February 2006

Focus on Safety Rather Than Harm

The 8th EMEA-IFAPP Conference in London during February 2006 focused on pharmaceutical medicine risk management considerations, outlined details of an overall risk management system and European Risk Management Strategy (ERMS) in particular.

Dr Barry Arnold, Vice President Clinical Drug Safety, AstraZeneca, highlighted that the aim of a risk management system is to ensure that the benefits of a particular medicine exceed the risks by the greatest achievable margin for the individual patient and for the target population as a whole. This can be done by increasing benefits or by reducing risks. However by its definition, risk management focuses upon the risk reduction approach. As Dr June Raine from the Medicines and Healthcare Products Regulatory Agency (MHRA) in London, United Kingdom, pointed out, the emphasis of risk management today focuses on safety rather than harm with the aim of extending safety knowledge over time and safeguarding users from serious adverse drug reactions (ADRs).

General Principles

Enhancing drug safety in the 21st century means increasing evidence, applying a more proactive conduct of pharmacovigilance, finding the right balance between timely access for patients to medicines and the knowledge needed on medicine safety profile at the point of licensing, along with the most robust post-licensing program, explained Dr Noel Wathion from the European Medicines Agency (EMEA). Risk Management Plans will be an important tool in contributing to achieving these goals.

"A risk management system is a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to medicinal products, and the assessment of the effectiveness of those interventions" (CHMP Guideline 14 November 2005 – EMEA/CHMP/96268/2005). As Dr Wathion pointed out, a risk management system requirement can be fulfilled by the submission of a European Risk Management Plan (EU RMP).

According to ICH E2E, Part I of the EU RMP contains safety specification and the Pharmacovigilance Plan. Part II evaluates the need for risk minimization activities and – if a need for additional activities is apparent – the Risk Minimization Plan. This is likely to mirror the-Pharmacovigilance Plan outline, but also may include assessment of effectiveness.

Regulatory Perspectives

Dr Wathion noted that the first phase of the European Risk Management Strategy (ERMS) has been finalized. It focused on improving operational and organizational aspects of the pharmacovigilance component of the EU Regulatory System and on improving the spontaneous reporting scheme. The second phase has started with a two year rolling work plan up to mid 2007. It focuses on implementation of new community legislation, complementary implementation initiatives and EU Pharmacovigilance System (EU PhV) strengthening.

New legislative tools primarily relate to the introduction of a toolkit (e.g., Risk Management Plans) to provide an adequate public health protection while not delaying timely access to medicines as well as providing better transparency in the medicine safety field . In this regard article, 8 (3)(ia) of Directive 2001/83/EC requires the Marketing Authorization Applicant (MAA) to submit "a detailed description of the pharmacovigilance and, where appropriate, of the risk management system which the applicant will introduce."

The pharmacovigilance system is company-specific, not product-specific. It will be covered in the "Guideline on the monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections", which is under development.

Beyond Regulatory Requirements

Valerie Simmons, Eli Lilly, United Kingdom, suggested that the industry should think beyond just satisfying regulatory requirements and focus on an anticipatory, systematic and data driven approaches to evaluating safety (risk assessment). Additionally manufacturers should consider what they will do when important safety issues are identified (risk minimization). It is appropriate to start planning risk management early in the development process, based on non-clinical data and information on closely related compounds.

Simmons has specified numerous pre-approval risk management principles:

- Establish a procedure and a multi-disciplinary Safety Management Team (SMT).
- Determine background data and ready accessibility of all safety data.
- Involve epidemiologists, anticipate disease related events, consider target benefit-risk profile and ensure processes in place for all safety data sources to be available to the SMT.
- Develop a proactive approach and establish time frames, milestones and decision-making procedures.
- Establish advisory bodies with an internal senior executive safety committee, which reviews and responds to SMT issues with an ad hoc external expert advisory panels (issue-specific).
- Define the role of the Data Safety Monitoring Board (DSMB).
- Identify all known or anticipated risks and consider any potential for new risks from safety issues, potential high-risk populations or circumstances like medication errors or off-label use.

Simmons concluded: "The art of good risk management is finding and dealing with the right safety signals, not just identifying more signals." Eckhard Boettcher-Buehler

Presentations and Abstracts from the 8th EMEA-IFAPP Conference are available on IFAPP's website at www.ifapp.org following the menu "news" > "latest news" > "archive" under the headlines "2006 March" and "2006 June".

THE FLAG

IFAPP World is a publication of the **International Federation of Associations of Pharmaceutical Physicians (IFAPP)**

The Federation, founded in 1975, is a non-profit organization with 29 national Member Associations worldwide.
IFAPP acts as an international forum for all Pharmaceutical Physicians organizations worldwide by dealing with matters brought to its attention through national Member Associations.

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The World in Brief

Korean Government

US$ 450 Million on Stem Cell Research Proposed

May 2006 • The Korean government set-up a plan to channel roughly US$ 454 million into stem cell research over the next decade. "Currently, our competitive ranking in stem cell research would be at the seventh or eighth spot in the world," said Ministry of Science and Technology official – according to a notice on from the Korean Overseas Information Service (KOIS) of the Government Information Agency. "With large-scale investment, we look to become one of the world's top three powerhouses in the potential-laden stem cell segment by 2015," he added.

The budget will be spent both on adult and embryonic stem cells research and used to strengthen experiment ethical standards. Also included are studies on the stem cell's differentiation mechanism, establishment of a clinical test database and a system to set-up stem cell banks. Korea expects the investment to dispel any remaining jitters caused by the scandal involving stem cell scientist Hwang Woo-suk as well as provide fresh momentum for the country's biotechnology initiative.

The ministry also decided to funnel US$ 845 million into biotechnologies this year alone, up 18.9 percent year to year. More than 80 percent of the funds will go to biotechnology research while the remaining will be used to help build infrastructure. IFAPP ■

World Health Organisation and India's NIPER

TRIPS Not Impacting Drug Prices in India

June 2006 • A study researching the "Impact of TRIPS (Trade-Related Aspects of Intellectual Property Rights) on Pharmaceutical Prices, with specific focus on Generics in India," sponsored by the World Health Organization (WHO) and carried out by India's National Institute of Pharmaceutical Education and Research (NIPER), concluded:

"The Indian pharma industry is 'production oriented' – focusing on bulk production at cheaper cost, by developing new and improved processes, rather than trying to develop new molecules.

A large booming population ensures a market for low-priced generic medicines, which are not affected by TRIPS or changes in patent laws."

Biopharmaceutical Prices May Remain High

The same study also emphasized the need to develop Indian biopharmaceutical manufacturing technical skills in an effort to reduce prices for biologicals (e.g. erythropoetin, insulin, gamma IgG, colony stimulating factor, interleukins etc.). Otherwise prices are likely to remain high due to the lack of domestic competition.

"Interestingly, several of the patented biodrugs themselves are falling into the 'generics' category, their patents having expired or being on verge of expiry. But their prices are not likely to come down in the near future, owing to absence of domestic challenge. Hence, it is imperative that the pharma industry and the Indian government recognize this challenge and go into mission mode to bridge this gap," the study pointed out.

WHO/IFAPP ■

Stay Tuned

World Health Organization

Key Details to be Disclosed for Trial Registration

May 2006 • As part of the World Health Organization's (WHO) International Clinical Trials Registry Platform, a major initiative aimed at standardizing the way information on medical studies is made available to the public through a process called registration, the WHO is also recommending that 20 key details be disclosed at the time studies are begun. "Registration of all clinical trials and full disclosure of key information at the time of registration are fundamental to ensuring transparency in medical research and fulfilling ethical responsibilities to patients and study participants," said Dr Timothy Evans, WHO's Assistant Director-General, in a WHO press release.

WHO's planned Registry Platform will not be a register itself, but rather will provide a set of standards for all registers. According to the WHO, it has not only standardized what must be reported to register a trial but is creating a global trial identification system that will confer a unique reference number on every qualified trial and seeks to bring participating registers together in a global network to provide a single point of access to the information stored in them. Later this year, the WHO Registry Platform will launch a web-based search portal where scientists, patients, doctors and anyone else who is interested can search among participating registers for clinical trials taking place or completed throughout the world.

A Fair and Open Process with all Stakeholders

Although registration is voluntary, there is a groundswell of policies aimed at spurring registration of all clinical trials. In July 2005, for example, the International Committee of Medical Journal Editors, a group representing 11 prestigious medical journals, instituted a policy whereby a scientific paper on clinical trial results cannot be published unless the trial had been recorded in a publicly accessible registry at its outset.

Some groups have raised concerns that these new requirements could jeopardize academic or commercial competitive advantage if they apply to preliminary trials of new interventions. Similar concerns have been voiced about the requirement to disclose certain items – such as the scientific title of the study, the name of the treatment being tested and the outcomes expected from the study – at the time of registration.

"Our aim is to make clinical research transparent and enhance public trust in science, but we are engaged in a fair and open process with all stakeholders," said Dr Ida Sim, Associate Director for Medical Informatics at the University of California, San Francisco and coordinator of WHO's Registry Platform initiative.

WHO/IFAPP ■

For more information visit the website www.who.int/ictrp/en and for the Trial Registration Data Set www.who.int/ictrp/data_set/en/index1.html

IFAPP'S Regional Update: Argentina

Pharmaceutical Medicine in Transition

From Dr Eduardo de la Puente, President of the Argentinean Society of Pharmaceutical Medicine (Sociedad Argentina de Medicina Farmacéutica – SAMEFA)

What You Should Know

What you should know about Argentina's SAMEFA: IFAPP's President Elect, Dr Luis Francisco Collia, is from Buenos Aires, Argentina. Formerly he was the president of the Argentinean Society of Pharmaceutical Medicine (Sociedad Argentina de Medicina Farmacéutica – SAMEFA) and has been SAMEFA's delegate to IFAPP since 1998.

From A.M.A.I.F.A. to SAMEFA

In fact, there was not a single founder of the Argentinean association, but rather a group of physicians who began working as advisors to the pharmaceutical industry 30 years ago. The original name was Asociación de Médicos Asesores de la Industria Farmacéutica Argentina (A.M.A.I.F.A.), Association of Medical Advisors of the Argentinean Pharmaceutical Industry.

Over time the purpose of this association changed from just gathering like-minded physicians with a determined working link to a more ambitious mission with increasing relevance: impart knowledge, exchange experience and generate expertise in pharmaceutical medicine. As a consequence, the descriptive name of the association was changed to a more programmatically term: Sociedad Argentina de Medicina Farmacéutica – SAMEFA.

The Significant Difference

The purpose of pharmaceutical medicine as a new medical specialty is to offer physicians and their patients new effective and safe drugs. However, pharmaceutical medicine is quite different from pharmacology.

Generally, pharmacology is dedicated to discovering new substances or creating new molecules by screening or molecular design and studying its mode of actions within the human body. Pharmaceutical medicine is focused on how to transform such active substances to potent and promising drugs, to apply for the drug's approval and bring it to the market. This entire process is based on accurate, systematic and reliable scientific research and development as well as faithful and fair communication and commercialization as well as – last but not least – a continuing monitoring of all its effects in daily practice.

A Broader Scope

Argentinean specialists in pharmaceutical medicine primarily work within the pharmaceutical industry and contract research organizations (CROs). However, the scope of specialists' activities in pharmaceutical medicine is much broader and goes from teaching and training to guiding, regulating and governing. Indeed, the number of such specialists working for the Argentinean National Administration of Drugs, Food and Medical Technology (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica –ANMAT-) or other non-commercial organizations has increased tremendously in the past few years.

SAMEFA's database currently counts more than 100 professionals with a degree in pharmaceutical medicine. However this does not fully reflect the high interest of Argentinean physicians in pharmaceutical medicine, which has increased in parallel to their interest in clinical research. Why is this the case? When pediatricians, cardiologists, gynecologists or other medical specialists get involved in clinical research, they often face challenges in fulfilling all of the required rules and regulations, therefore calling upon other professionals for expertise in pharmaceutical medicine. This is why over 300 physicians have already specialized in this discipline, but without a degree, and many more are interested in gathering pharmaceutical medicine know-how.

The ever-increasing interest in pharmaceutical medicine is most welcome and SAMEFA has reinforced this development through its activities as well as willingly offering information and education in pharmaceutical medicine.

In Transition

Serving this growing demand, SAMEFA has established specific courses for researchers, clinicians and practitioners, as well as investigators, coordinators and monitors. Additionally, SAMEFA is co-publisher of the magazine "Distinguished Works in Pharmaceutical Medicine", a collaborative work with the Iberoamerican Society of Scientific Information (Sociedad Iberoamericana de Información Científica – SIIC), having just launched its third volume.

Pharmaceutical medicine in Argentina currently requires post-graduate training, which suits specialized physicians as a top-up qualification. However the idea is to raise pharmaceutical medicine to a status comparable to cardiology or any other medical specialty.

Since 1996 SAMEFA has been committed to this idea organizing a special program for structured education in pharmaceutical medicine for physicians. In 2003 this program was recognized and approved by the Faculty of Medicine of the University of Buenos Aires (UBA) and their Superior Council. Recently SAMEFA has filed an application to finally transform pharmaceutical medicine to a university degree program. Once this has been approved and the course accredited by the IFAPP, the post-graduate degree awarded by SAMEFA will be of international value and identify an international medical specialist in pharmaceutical medicine. ■

Media Scope

The Wall Street Journal Europe in April 2006

How Reliable are Industry Sponsored Trials

»When psychiatrist John Davis analyzed every publicly available trial funded by the pharmaceutical industry pitting five new antipsychotic drugs against one another, nine in 10 showed that the best drug was the one made by the company funding the study. "On the basis of these contrasting findings in head-to-head trials, it appears that whichever company sponsors the trial produces the better antipsychotic drug," Dr Davis and others wrote in the American Journal of Psychiatry.

Now an increasing chorus of experts is asking whether the research establishment needs to be reoriented toward publicly funded studies that might better guide clinical decisions and the billions of tax dollars the government itself spends on treatment. "A perfectly independent agency has to be set up that says, `Here are the areas where trials must be done," said Drummond Rennie, deputy editor of the Journal of the American Medical Association.«

»The problem isn't that companies fabricate results, experts say. Researchers, in fact, want drug makers to sponsor more studies, not fewer.« ■

IFAPP News

Poll amongst IFAPP's national member associations

High Satisfaction with Services and Communication

Recently IFAPP conducted a poll amongst IFAPP's national member associations on IFAPP services and communication as well as on Pharmaceutical Medicine ethics . Out of 29 national member associations, 18 responded (62%) and completed the IFAPP's questionnaire: South Africa, Belgium, Switzerland, United Kingdom, Italy, Korea, Greece, Ireland, Argentina, Netherlands, Turkey, Australia, USA, Brazil, Indonesia, Pakistan, Germany and one anonymous country. The results were generated in May 2006. Details regarding the subject communication are summarized as followed:

A key question was: *Please rank the importance of the current services that IFAPP provides.*

Most important for IFAPP members, and in accordance with IFAPP's mission, are education, accreditation and training in Pharmaceutical Medicine and assistance in establishing adequate courses. Additionally, an overall promotion of the recognition of Pharmaceutical Medicine as a medical specialty was a priority. The answers in detail are shown in figure 1.

In response to: *Are you satisfied with the frequency of communication from IFAPP?* 13 out of 18 answered, the communication is "about right," 4 found it "infrequent," but none said it is "too frequent" or "very un-frequent".

Considering *Overall, how satisfied are you with the service that IFAPP provides to your member association?* answers were:

"Very satisfied" 2, "satisfied" 8, "neutral" 6, "dissatisfied" 1, "very dissatisfied" 0 (see figure 2).

What specific suggestions do you have that will help us improve our service? receiving some interesting responses:

"Our association only uses the IFAPP services sporadically, as the mission of the local association is to support the members in their working environment in our country and [it] deals mostly with country specific issues."

"We would be better to think about whether the TC [teleconference] with only EC [Executive Committee]members is appropriate, and is there another way to communicate with the member associations."

"Try to involve new countries in IFAPP, especially from Eastern Europe (Baltic countries) and Africa (e.g. Mozambique, Zimbabwe, even Egypt)."

"Education, accreditation and training in Pharmaceutical Medicine; assistance in establishing courses in Pharmaceutical Medicine and promotion of recognition of Pharmaceutical Medicine as a medical specialty."

"I suggest a more frequent IFAPP bulletin or newsletter as a tool for information exchange among member associations."

"Collaboration with the Drug Information Association (DIA) and the Association of Clinical Research Professionals (ACRP), joint meetings, IFAPP speakers in local associations etc."

Eckhard Boettcher-Buehler

A summary regarding the poll's results on ethics in Pharmaceutical Medicine will be presented in the next issue of IFAPP World – coming in october 2006.

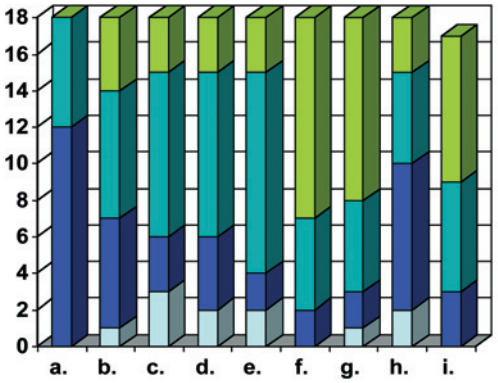

Figure 1

a. pharmaceutical and country news
b. international conference on Pharmaceutical Medicine
c. conferences involving EMEA
d. conferences involving FDA
e. ethical code of conduct
f. education, accreditation and training in Pharmaceutical Medicine
g. assistance in establishing courses in Pharmaceutical Medicine
h. assistance in establishing member associations
i. Promotion of recognition of Pharmaceutical Medicine as a medical specialty

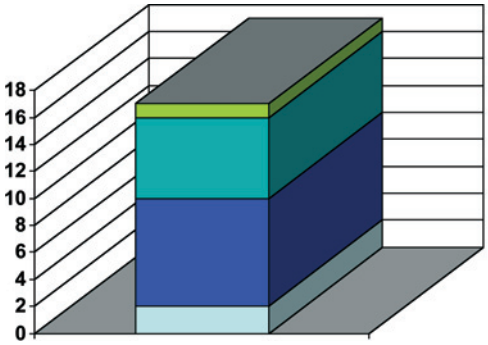

Figure 2

Welcome to IFAPP WORLD

Welcome to the world of IFAPP – enjoy IFAPP WORLD!

You are kindly invited to contribute ideas, suggestions, advice and articles to make IFAPP World a lively, interesting and varied newsletter for readers all over the world.

Your considerations, questions or comments are very welcome.

Please share with the editorial board representative Dr Johanna Schenk at johanna.schenk@pharmaprojekthaus.com or with IFAPP World editor-in-chief Eckhard Boettcher-Buehler at boebue@t-online.de.

Dates & Deadlines

3-6 September 2006 • Seoul, Korea
ICPM 2006 – 14th International Conference on Pharmaceutical Medicine

Hosted by the Korean Society of Pharmaceutical Medicine (KSPM) and the International Federation of Associations of Pharmaceutical Physicians (IFAPP) in collaboration with four other Korean societies and associations. *Detailed information is available at www.icpm2006.org and in this IFAPP World issue on pages 1,2, 10-13.*

6-8 September 2006 • Seoul, Korea
BIO KOREA 2006 – Conference and Exhibition

Organized by the Korea Health Industry Development Institute (KHIDI) and the Korea International Trade Association (KITA). *Detailed information is available at www.biokorea.org – also please pay your attention to the special note "Why Don't You Join BIO KOREA 2006 After ICPM?" in this IFAPP World issue on page 3.*

16-20 September 2006 • Vrsac, Serbia
4th European Summer School in Clinical Pharmacology & Therapeutics

In the long lasting collaboration between IFAPP and EACPT (European Association for Clinical Pharmacology and Therapeutics) IFAPP is supporting the CPT Summer School 2006. The 4th Summer School has become CME accredited by the Faculty of Pharmaceutical Medicine in London, UK, and the Medical Faculty, University of Kragujevac, Serbia.
Detailed information is available at www.eacpt.vrsac.com in the worldwide web.

5-6 October 2006 • S.A.S. Nagar, Punjab, India
Indo-US Symposium on Nanotechnology in Advanced Drug Delivery

Organized by the National Institute of Pharmaceutical Education and Research (NIPER) and the Indo-U.S. Science and Technology Forum. *Detailed information is available at www.niper.nic.in/Indo-US-nanotechnologydrugdelivery.html in the worldwide web.*

Media Scope

Court Of Justice of the European Communities in May 2006

Obligation to Reimburse Treatment Costs All Over the EU

The European Court of Justice recently confirmed that national health services (NHS) of European Union's member states must reimburse a treatment, which a patient is obliged to get elsewhere in Europe because of hold-ups or long waiting lists in the Member State of residence. »The Court finds that, in order to be entitled to refuse to grant authorization on the ground of waiting time, the competent institution must establish that the waiting time, arising from objectives relating to the planning and management of the supply of hospital care, does not exceed the period which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned.«

»It was not about the money, it was about the principle. It was about getting my hip fixed,« said 75-year old Yvonne Watts from the United Kingdom, who brought the verdict in case, in a release of Press Association Ltd. According to that release, »The Department of Health had argued in court, that if all NHS patients were guaranteed reimbursement of their medical costs when they opted for treatment abroad, it would seriously undermine the NHS system of administering medical priorities through waiting lists.«

The Seattle Times in May 2006

Selling Confidential Trial Results to Wall Street

The Seattle Times, a daily U.S. newspaper, recently reported that »Wall Street brokers actively seeking inside information and are paying doctors and others who are performing clinical trials to break their confidentiality agreements and disclose information about the trial results before the information is released to the general public.« This practice already is subject of an investigation, since it may constitute insider trading. And – according to The Seattle Times – this story has generated reactions:

»The issue of any doctors selling such information to Wall Street was disconcerting. One of our concerns was the possible contamination of the quality of the research«, said Ramsey Flynn, associate editor of Hopkins Medicine magazine from Johns Hopkins Medical Center in Baltimore.

IFAPP's Vision Statement

IFAPP's Vision Statement

The IFAPP Executive Committee agreed in its 12 April 2006 meeting on the following new vision statement:

„By 2011, IFAPP is recognized and accepted as an authoritative voice on the medical aspects of the pharmaceutical industry and education and standards within pharmaceutical medicine by governmental and regulatory authorities, pharmaceutical industry bodies, the public, healthcare providers, healthcare professionals, academic bodies and the media."

Stay Tuned

Foundation of the European CRO Federation

End 2005 • Delegates representing the local contract research organizations (CRO) associations from the Netherlands, Germany, Czech Republic, France, Spain, Italy and United Kingdom held its inaugural meeting of the "European CRO Federation" (EUCROF) in Amsterdam, Netherlands. The aims and objectives of EUCROF were defined as:

- Promote the European Union for clinical research.
- Harmonize and actively promote the highest quality standards of clinical research.
- Focusing their strengths to bring more productive discussions with European bodies (EMEA, EU Parliament, Commission).
- Exchange information between the members.
- Propose thematic discussions with pharmaceutical industry representatives e.g. Pharmaceutical Contract Management Group (PCMG) to enhance business relations and identify common causes.
- Develop transcontinental relationships with other Associations, e.g. Association of Clinical Research Organizations (ACRO; USA), Japanese CRO Association (JCROA; Japan).

EUCROF will be established in The Netherlands; members are national associations of CROs. The current seven associations are representative of the local CROs network and represent as of today 250 companies.

EUCROF's first elected President is Mr Pieter Guelen, The Netherlands, Vice-President is Mrs Dagmar Chase, Germany. ■

ICPM 2006 – Scientific Program

The 14th International Conference on Pharmaceutical Medicine Seoul, Korea

16 CPD Credits Approved – For details: www.icpm2006.org

September 3, 2006 (Sun)

9:00~15:00	**Meeting of IFAPP's Executive Committee**
15:30~17:00	**Meeting of IFAPP's House of Delegates**
18:00~18:30	**Welcome & Opening Ceremony**
Opening Lecture 18:30~19:30	*Chair: Chris Allen, Merck (USA) / Co-Chair: Yil-Seob Lee, GSK (Korea)* *Juhana E. Idänpään-Heikkilä. CIOMS (Switzerland)* *Arthur Atkinson, Northwestern University (USA)*
19:30~21:30	**Welcome Reception**

September 4, 2006 (Mon)

Session A **08:30~10:00**	**Clinical Trials: Experiences in the Emerging Market** *Chair: Ross Horsburgh, AstraZeneca (AP)* *Co-Chair: Tsutae Nagata, GSK (Japan)*
08:30~08:50	**Asia** *Jorge Puente, Pfizer (Asia)*
08:50~09:10	**Clinical Trials in China** *George Chen, GSK (China)*
09:10~09:30	**Latin America** *Daniel Mazzolenis, Thywill LatAm Solutions SRL (Argentina)*
09:30~09:50	**Eastern Europe** *Gerfried Nell, NPC Nell Pharma Connect Ltd. (Austria)*
09:50~10:00	Discussion
10:00~10:30	Coffee Break / Commercial Exhibition / Poster Presentation
Session B **10:30~12:00**	**Clinical Trials: Opportunities and Challenges in Asia** *Chair: Jennie Sykes, GSK(UK)* *Co-Chair: Kihito Takahashi, Banyu Pharmaceutical Co., Ltd (Japan)*
10:30~11:00	**Regulatory Authorities Aspect** *Kazuhiko Mori, PMDA (Japan)*
11:00~11:30	**Social and Cultural Aspect** *Greg Voinov, MDS Pharma Services (France)*
11:30~12:00	**Human Resources in Asia** *Frank Fan, Abbott (China)*
Luncheon Symposium **12:00~13:30**	**"Focus on the Patient: The Importance of Proactive Pharmacovigilance"** *Chair: Sree Haran, GSK (UK) / Speaker: Steve Hobbiger, GSK (UK)*

ICPM 2006 – Scientific Program

Session C **13:30~15:00**	**Ethics in Pharmaceutical Medicine** *Chair: Sutinder Bindra, Pfizer (AP) / Co-Chair: Paul Jang, MSD (Korea)*
13:30~14:00	**Ethics in Biomedical Research** *Jane Barrett, The Barrett Consultancy (UK)*
14:00~14:30	**Ethics in Pharmaceutical Business Practice** *Pol Vandenborucke, Pfizer (Japan)*
14:30~15:00	**Ethical Issues in Stem Cell Research: Experience in Korea** *Ock-Joo Kim, Seoul National University (Korea)*
CPE Session **13:30~15:00**	**Clinical Research Project Management** *Chair: Hye-Yeon Park, Janssen (Korea)*
13:30~14:00	**Budget Management in Clinical Trials** *Hye-Jong Yoo, AstraZeneca (Korea)*
14:00~14:30	**Clinical Study Patient Recruitment Strategies** *Ling Su, Roche (China)*
14:30~15:00	**Outsourced Clinical Research Management** *Jeong-Ae Kim, LGLS (Korea)*
15:00~15:30	Coffee Break / Commercial Exhibition / Poster Presentation
Session D **15:30~17:00**	**How to Improve Access to Medicine** *Chair: Bong-Min Yang, Seoul National University (Korea)* *Co-Chair: Stephen Phua, IMS (Singapore)*
15:30~16:00	**Regulatory Approval** *Zili Li, Merck (USA)*
16:00~16:30	**Pricing and Reimbursement** *Domenico Criscuolo, ICON (Italy)*
16:30~17:00	**Informed Patients** *Johanna Schenk, PharmaProjekthaus GmbH & Co.KG (Germany)*
CPE Session **15:30~17:00**	**QA & QC in Clinical Trials** *Chair: Dong Seob Kim, KFDA (Korea)*
15:30~16:00	**QA & QC under GCP Environment** *Hannah Chen, GSK (China)*
16:00~16:30	**Audit and Inspection** *Stephen Kendal, AstraZeneca (UK)*
16:30~17:00	**Best Practice Sharing** *Gary Wilson, Pfizer (USA)*

ICPM 2006 – Scientific Program

September 5, 2006 (Tue)

Session E **08:30~10:00**	**Pharmaceutical Medicine** *Chair:Pintens Henri (Belgium)* *Co-Chair: Churl J. Kim, Handok Pharmaceutical (Korea)*
08:30~09:00	**Pharmaceutical Medicine as a Specialized Discipline of Medicine** *Peter Stonier, Faculty of Pharmaceutical Medicine (UK)*
09:00~09:30	**Pharmaceutical Medicine Specialization in Europe: Is the model exportable elsewhere?** *Madeleine Billeter, AstraZeneca (Switzerland)*
09:30~10:00	**Development of Pharmaceutical Medicine Specialty in Asia** *Kyoko Imamura, Janssen Pharma (Japan)*
10:00~10:30	Coffee Break / Commercial Exhibition / Poster Presentation
Session F **10:30~12:00**	**New Initiatives in Pharmaceutical Medicine Training** *Chair: Rick Sax, AstraZeneca(USA) / Co-Chair: Chris Bruenger, IDA(Japan)*
10:30~11:00	**In House Education in Pharmaceutical Medicine for Physicians and Scientists – the AstraZeneca Experience** *Carl David Sundstedt, AstraZeneca (Sweden)*
11:00~11:30	**GSK Academy: A 'Centre of Excellence' in Pharmaceutical Medicine** *Sree Haran, GSK (UK)*
11:30~12:00	**Pfizer Development Program** *Honorio Silva, Pfizer (USA)*
Luncheon Symposium **12:00~13:30**	**"Value of Innovative Medicine"** *Chair: Chris Allen, Merck (USA)*
Session G **13:30~15:00**	**Biomarker in Drug Development** *Chair: Marleen Verlinden, Abbott(USA)* *Co-Chair: SG Shin Seoul National University(Korea)*
13:30~14:00	**Biomarkers and Surrogate Endpoints, For What Purposes Are They Fit?** *Arthur Atkinson, Northwestern University(USA)*
14:00~14:30	**New Biomarkers in Clinical Development** *Howard Lee, University of Pittsburgh(USA)*
14:30~15:00	**Biomarker Discovery: Proteomics Approach in Korea** *Myung-Hee Yoo, KIST(Korea)*
CPE Session **13:30~15:00**	**Document Writing in Clinical Research** *Chair: Yoon-Koo Kang, Asan Medical Center(Korea)*
13:30~14:00	**Investigator Brochure** *Keum-Ah Oh, Yuhan(Korea)*
14:00~14:30	**Protocol / CRF** *Sungku Choi, Janssen(Korea)*
14:30~15:00	**A Team-Based Approach to Creating a Clinical Study Report** *Nicholas Waters, PRA International(USA)*
15:00~15:30	Coffee Break / Commercial Exhibition / Poster Presentation

ICPM 2006 – Scientific Program

Session H **15:30~17:00**	**Drug Safety Management** *Chair: Jee-Woong Son, AstraZeneca(Korea)* *Co-Chair: Byeong-Ju Park, Seoul National University(Korea)*
15:30~16:00	**Safety Evaluation in Clinical Trials** *Won Choi, GSK(Korea)*
16:00~16:30	**Post-Authorization Safety** *Stewart Geary, Eisai co. Ltd. (Japan)*
16:30~17:00	**Pharmacovigilance Planning in Risk Management** *Ken Hartigan Go, ISoP (Manila)*
CPE Session **15:30~17:00**	**Qualification of CR Professionals** *Chair: Cheong, Yuet-Meng, Pfizer (Asia)*
15:30~16:00	**Certification of Physicians and non-physicians in the US** *Lou Sherwood, APPI (USA)*
16:00~16:30	**Europe**
16:30~17:00	**Postgraduate Courses and Certification on Pharmaceutical Medicine in Latin America** *Luis Collia, ELEA (Argentina)*
19:30~21:30	**Gala Dinner**

September 6th, 2006 (Wed)

Session I **08:30~10:00**	**Cutting-Edge Technology in Drug Development** *Chair: Mark A Bach, Merck (USA)* *Co-Chair: Dong-Ho Lee, Samyang (Korea)*
08:30~09:00	**Accelerating Drug Discovery Based on StructuralChemoProteomics** *Joong Myung Cho, Crystal Genomics (Korea)*
09:00~09:30	**Identification of Novel Drug Target Utilizing Genomics, Proteomics and In silico Technologies** *Yasuhiro Hashimoto, MediBic (Japan)*
09:30~10:00	**Imaging in Drug Discovery and Development** *Richard Hargreaves, Merck and Co. (USA)*
10:00~10:30	Coffee Break / Commercial Exhibition / Poster Presentation
Session J **10:30~12:00**	**Pharmacogenomics** *Chair: Ron Krall, GSK(USA)* *Co-Chair: Jae-Gook Shin, InJe University Hospital (Korea)*
10:30~11:00	**Pharmacogenomics and Its Application** *Allen Rose, GSK (USA)*
11:00~11:30	**Regulatory Perspective to use Pharmacogenomics in Clinical Drug Development and Future Direction of Pharmacogenomics** *Yoshiaki Uyuama*, PMDA (*Japan*)
11:30~12:00	**Pharmacogenomics – Perspectives from Pharmaceutical Industry** *Paul Dai, Novatis (China)*
12:00~13:00	**IFAPP General Assembly**
13:00~13:30	**Highlight of ICPM 2006** **Closing Ceremony** **Preamble 2008 Meeting**

"See you at ICPM 2006 in Seoul, Korea"