IFAPP WORLD
International Federation of Associations of Pharmaceutical Physicians
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CONTENT



Pharmacovigilance

# Issues in International Drug Safety Management

*Dr Stewart Geary, Member of IFAPP's Executive Committee, Tokyo, Japan*

Professionals working in pharmacovigilance enjoy the unique privilege of working for the benefit of patients at the interface of pharmacology, medicine and pharmacoepidemiology in the development of new and the continuing evaluation of existing drugs and medical devices. We work in an international environment and many of our challenges stem from the difficulty in harmonizing drug safety management across borders. Two such challenges are described as follows: ▶ page 5

Questions & Answers

# Towards a 'European Federation of Courses in Pharmaceutical Medicine'

## IFAPP Initiative on Education in PM

On 7 June 2007 IFAPP's 'European Chapter' of the 'Council for Education in Pharmaceutical Medicine' (CEPM) held a meeting in Brussels, Belgium, with the directors of postgraduate courses in Pharmaceutical Medicine from major European universities. The purpose of the meeting was to have a face-to-face discussion for a specific proposal: the opportunity and feasibility of a joint body representing European postgraduate courses in Pharmaceutical Medicine – a 'European Federation of Courses in Pharmaceutical Medicine'. The desirability of this objective has been sparked off by the 'Innovative Medicines Initiative' (IMI).

*Dr Juan Lahuerta, Chairman of the 'European Chapter' of CEPM, Madrid, Spain*

Details on the objectives and the meeting's results are addressed by Dr Juan Lahuerta, Chairman of the 'European Chapter' of CEPM, in the following interview with Eckhard Boettcher-Buehler.

*IFAPP WORLD • Dr. Lahuerta, what exactly is the 'Innovative Medicines Initiative' all about?*

*Dr Lahuerta* • IMI is a proposed partnership launched by the 'European Commission' and the 'European Federation of Pharmaceutical Industries and Associations' (EFPIA). ▶ page 2

President's Letter

# Dear Colleagues

During IFAPP's last Executive Committee face-to-face meeting in Vienna last March – for details see page 4 – we reviewed our achievements, analyzed the ongoing initiatives and discussed our future plans. Delegates from 16 countries were involved.

As a conclusion to our discussion, we summarized several important strategic issues, which have to be further elaborated. To achieve this, we have established a committee led by Dr Sander Becker, that shall further shape options and visions regarding IFAPP's strategic direction. We are curious to follow the results, which can be expected within 12 months.

*Dr Luis F. Collia, IFAPP President*

I kindly remind you that on the 19 October 2007 the 9th European IFAPP Conference will be held in London, UK, nearby the headquarters of the 'European Medicines Agency' (EMEA), at the Hilton Docklands Hotel, Canary Warf. The conference will be co-sponsored by the 'British Association of Pharmaceutical Physicians' (BrAPP), an IFAPP member association celebrating its 50th anniversary this year.

IFAPP has secured important speakers for the conference from the EMEA and ▶ page 2

## President's Letter

◀ other European organizations. The conference key topic is "Europe's Role in Clinical Research: Challenges and Opportunities" which includes the following issues: "The Impact of the EU Directive on Clinical Trials", discussed in the morning session, and "The Emerging Role of Europe in Paediatric Development" addressed in the afternoon.

Focusing upon scientific activities, I would like to remind you of two other important meetings: the EACPT-IFAPP Symposium on 30 August 2007 at the Congress of the 'European Association for Clinical Pharmacology and Therapeutics' (EACPT), and the '15th International Conference on Pharmaceutical Medicine' (ICPM 2008) in September 2008, both in Amsterdam, the Netherlands.

Planning and preparation for ICPM 2008 is in full swing as I discovered while visiting Amsterdam to meet Dr Rudolf van Olden, Chairman of the 'Netherlands Association of Pharmaceutical Physicians' (NVFG) and Chairperson of ICPM 2008, Dr Paul van Meurs, Secretary ICPM 2008, and George Brouwer, congress manager. I got assured the organization is on the right way to successfully manage the meeting to the benefit of IFAPP and all of us. I also would like to thank the organizers and all delegates of Member Associations who nominated speakers with true expertise in their fields.

Recently, by the initiative of IFAPP's 'Council for Education in Pharmaceutical Medicine' (CEPM), a Forum was created in Brussels, Belgium, to discuss harmonization of courses and the mutual recognition of diplomas in Pharmaceutical Medicine in Europe as well as to establish a 'European Federation of Courses in Pharmaceutical Medicine'. It will be joined by directors of postgraduate courses in Pharmaceutical Medicine from major European universities. Dr Juan Lahuerta, Chairman of the European Chapter of CEPM, presents details of this initiative in an interview featured in this issue of IFAPP World.

Last but not least it is my pleasure to congratulate the newly elected presidents of the Serbian Society, Dr Milica Prostran, and the Hungarian Society, Dr Zoltán Hosszú, who recently assumed these positions. Then I thank all of you for your active participation in IFAPP's operations.

*Dr Luis Francisco Collia,*
*IFAPP President and Medical Director ELEA,*
*Buenos Aires, Argentina* ■

## Questions & Answers

◀ In IMI's 'Strategic Research Agenda' (SRA – for details see next page) education and training in Pharmaceutical Medicine is highlighted as one of the areas where improvement is necessary in Europe, so that our continent remains competitive in drug discovery and development with other parts of the world, notedly North America.

*IFAPP WORLD • How does IFAPP's 'European Chapter' of CEPM relate to the 'Innovative Medicines Initiative'?*

*Dr Lahuerta* • The 'Council for Education in Pharmaceutical Medicine' (CEPM) was established as a permanent group within IFAPP in 2001. The objectives of CEPM are: to harmonize the content of the programs of education in Pharmaceutical Medicine (PM) and to accredit postgraduate courses in PM (PGcPMs), to assist universities to establish additional PGcPMs and national Member Associations (nMAs) in setting up programs of CME and CPD, to promote the mutual recognition of diplomas in PM awarded by the PGcPMs accredited by IFAPP, to obtain the recognition of the title of physician specialist in PM internationally.

With the inception of the 'Innovative Medicines Iniative' (IMI) a clear opportunity seems to emerge for the fostering of education and training in PM in Europe. In order to focus on this particular opportunity and since the needs and undertakings are specific to the 18 European nMAs of IFAPP, it was proposed – and agreed by IFAPP's Executive Committee – earlier this year to set up a 'European Chapter'. This will help to provide focus and channel efforts of those nMAs involved without disturbing the tasks conducted by CEPM. All European nMA representatives remain members of CEPM and continue to take part in its various activities.

*IFAPP WORLD • Well. But why do we now need a 'European Federation of Courses in Pharmaceutical Medicine'?*

*Dr Lahuerta* • It is perceived wisdom that the whole is more than the sum of its parts. European courses in PM, although each different in some aspect or another, share a common ground of interests and needs. CEPM has debated about how to best address these and came to this suggestion. In a way, this is no different to what we have established for ourselves: the 'European Chapter'. Thus, if it works well for us, why not for the courses? The IMI calls for European concerted efforts. A European platform representing a variety of individual stakeholders will be in a better position to take part in any proposed program and activity. As you can see, there is a gamut of benefits to be gained by associating courses in Europe and CEPM can likewise benefit from this.

*IFAPP WORLD • What will be the strengths and assignments of the prospected new federation? Are there any principal differences compared to the CEPM?*

*Dr Lahuerta* • These are still to be defined and agreed by their members: the representatives of European courses in Pharmaceutical Medicine. The role of the 'European Chapter' was to facilitate the process and provide initial support to the federation.

The objectives of this proposed Federation, discussed at the meeting, were highly comprehensive and ambitious:

- Foster communication and interaction between the various courses in Pharmaceutical Medicine and the CEPM.
- Assist national member associations in creating additional postgraduate courses in Pharmaceutical Medicine and in launching continuing medical education (CME) and continuing professional development (CPD) for Pharmaceutical Physicians, harmonize and accredit existing courses, work towards mutual recognition of diplomas in Pharmaceutical Medicine and promote Pharmaceutical Medicine as a new medical specialty.

▶ page 3

## For the Record

**IFAPP CEPM**

**Council for Education in Pharmaceutical Medicine (CEPM)** • The CEPM was created in 2001 under the auspices of IFAPP. Its main objective was to undertake the task to harmonize the programs of the existing postgraduate courses in Pharmaceutical Medicine. The CEPM is also prepared to assist IFAPP's national member associations and Universities in any new initiative in the establishment of additional postgraduate courses in Pharmaceutical Medicine and the setting up of continuing medical education (CME) and continuing professional development (CPD) programs.

▼

## Questions & Answers

◀ ● Bring together representatives of all European courses in Pharmaceutical Medicine and initiating the process of joining efforts towards the creation of a 'European Federation of Postgraduate Courses in Pharmaceutical Medicine'.

● And – last but not least – agree on the participation in the IMI-SRA project.

Although CEPM and the eventual federation share a common objective: fostering education and advancement in Pharmaceutical Medicine, the nature of the two organizations would be different. CEPM is composed of representatives of national associations of professionals of Pharmaceutical Medicine, while the proposed Federation would be made out of directors of academic-based postgraduate courses. The emphasis of CEPM is serving IFAPP's objectives and by promoting a strong and organized education in Pharmaceutical Medicine in Europe, I think that we strive towards that aim.

*IFAPP WORLD • A report prepared for the European Commission's Directorate General Enterprise dated November 2000 noted that the European research-based pharmaceutical industry is losing ground in terms of competitiveness including the discovery and development of new innovative medicines – what is behind this: limited budgets, poor incentives, overwhelming regulations, national barriers, lack of ideas, brain drain, shortfall of expertise and experts?*

*Dr Lahuerta* • Unfortunately for Europe this list is the bad news that we need to face up and change if we wish to remain at the forefront of drug development. Globalization takes its toll by directing activity to those more creative, efficient and productive. Having said this, I truly believe that European countries, and more specifically the European Union, will remain one of the most powerful players in drug development – if not the most powerful one. Europe has many important strengths and, if I had to single out one, it would be its people: more than 500 million of well-educated citizens. With the full incorporation of the Central and Eastern European countries, the opportunities for our continent to remain the engine of new and valuable drugs have expanded. With regards to Pharmaceutical Medicine, an area where expertise is sorely needed – as the IMI's SRA rightly points out – Europe is leading the way however. Well-trained Pharmaceutical Medicine professionals lead in many ways the course and conduct of drug development and lifecycle management. The move towards a "patient-centered" culture in the pharmaceutical industry is another critical factor to make of our chosen medical specialty a basic asset. Thus, I am very optimistic about the future of European Pharmaceutical Medicine and, it is really important that we make every effort to strengthen its position.

*IFAPP WORLD • Is the initiative towards a 'European Federation of Courses in Pharmaceutical Medicine' a means to strengthen Pharmaceutical Medicine or the status of pharmaceutical physicians?*

*Dr Lahuerta* • Being a physician myself, my heart tends to be closer to the needs for education of Pharmaceutical Physicians, having in mind that these courses are essential tools in the learning process for physicians developing a career within the pharmaceutical industry. Having said that, the multi-disciplinary aspect of Pharmaceutical Medicine has been recognized from its origin. Most courses accept professionals with academic backgrounds different than Medicine and lead to diplomas in Pharmaceutical Medicine. Therefore, the main focus is in Pharmaceutical Medicine by itself but no doubt, if the initiative progresses, physicians working in this specialty are likely to be particularly grateful since it would support our long held expectation that this discipline becomes a recognized medical specialty throughout Europe.

*IFAPP WORLD • Is there any suggestion of a European identity for Pharmaceutical Medicine experts even with all the different European healthcare systems?*

*Dr Lahuerta* • One of the key features of drug development is its worldwide scope. Although the medical needs are different in various parts of the world and the way healthcare is organized and delivered varies widely in the various European countries, the abilities required by Pharmaceutical Medicine professionals are universal and very easily transferable. In fact, drug development is a multinational activity and the usual setting is organized around European teams. On the other hand, the regulations brought by ICH and, in Europe, EMEA tend towards an even closer alignment of needs and requirements. In our cultural and business environment, a European identity is not an artificial one and, in many ways, complements the outlook brought by our colleagues from North America and other parts of the world. For a Spaniard that has worked in the UK, I can personally assure you that this is a real phenomenon.

*IFAPP WORLD • Correcting the relative underfunding of biomedical R&D in Europe is one goal of the 'Innovative Medicines Initiative's Strategic Research Agenda' (IMI-SRA). Well, will there be funding of education and training in Pharmaceutical Medicine too?*

*Dr Lahuerta* • We need to await the final "sign-off" of the proposal. All the information that we have and the planning documents I have seen go in that direction. Nevertheless, specific proposals with a ▶ page 4

### For the Record

**IMI and SRA**

**Innovative Medicines Initiative (IMI)** • IMI is a coordinated public and private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It will boost Europe's biomedical R&D base, help correct the relative underfunding of biomedical R&D in Europe compared to other regions of the world and create biomedical R&D leadership for Europe to benefit patients and society. Importantly, IMI will help to maintain and augment the European science base in order to make Europe more competitive and an attractive place for biopharmaceutical research investment.

**Strategic Research Agenda (SRA)** • The SRA describes recommendations on predicting safety and efficacy of new medicines as well as plans to bridge gaps in knowledge management and in education and training. These are the principal causes of delays in the complex process of discovering and developing new medicines. Over 350 senior representatives of patient organizations, universities, hospitals, regulatory authorities as well as of small and large biopharmaceutical companies worked together to produce the Strategic Research Agenda. It can be found at: www.imi-europe.org.

**Education & Training** • Goal: Europe should support the interdisciplinary E&T essential to the bioscience sector. Recommendations: Create a European Medicines Research Academy for education and training for professionals involved in biomedical R&D including regulatory officers over the whole lifecycle of a medicine. Map existing activities within E&T including identification of European centers of excellence and develop programs and implementation plans for the critical areas relevant to the biomedical R&D process. Foster mobility between academia and industry and Ph.D. programs to stimulate academia-industry interaction and support the identified need for scientists.

## Questions & Answers

◀ firm rationale and worthy objectives would need to be put together and are likely to compete for funding with similar projects on other key strategic areas the IMI-SRA defines, such as efficacy, safety and knowledge management. This could be an important area of collaboration between a European federation in Pharmaceutical Medicine courses and the 'European Chapter' of CEPM.

*IFAPP WORLD • With regard to IMI-SRA, which is initiated to create biomedical R&D leadership for Europe – will this strengthen the position of Pharmaceutical Medicine and help to promote Pharmaceutical Medicine as a medical specialty?*

*Dr Lahuerta* • This specific aim is spelled out in the IMI-SRA document. I believe this to be the case. Although at the end of the day it will be up to each individual country to decide on the merits of adding Pharmaceutical Medicine to the list of their recognized medical specialties – concerted efforts with harmonization of training requisites and education contents of curricula indeed is a very important step in that direction. In the movement towards a European "common house" we have experienced in our lifetime, reaching a critical mass of countries in which Pharmaceutical Medicine is a separate specialty will be a significant help to achieve this objective.

*IFAPP WORLD • Back to the 'European Chapter' of CEPM and the IFAPP: What are the next steps to further promote the initiative on education and training in Pharmaceutical Medicine? Who are the partners, and who is in the driving seat of the effort?*

*Dr Lahuerta* • We have just started our journey. After this initial meeting, we would continue to support the newly created "steering committee" of course representatives in any possible way. The next critical step could be putting together a joint proposal for education in Pharmaceutical Medicine as part of the IMI. There are many other areas of joint collaboration as indicated in the list I have numerated earlier. Obviously, the federation of courses will define its own priorities in due course and I hope we could set up a common agenda. The 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians' in the UK has also given its support to this initiative. As I said, the International Committee of the Faculty is a stakeholder of this project and I trust that we will continue to work together in the following months ahead.

*IFAPP WORLD • Once the 'European Federation of Courses in Pharmaceutical Medicine' is established – what is the role of IFAPP and CEPM? Will they remain involved and how can IFAPP further on maintain a stake in these developments?*

*Dr Lahuerta* • The CEPM would of course like remain involved in future developments. The relationship between IFAPP's national member associations and particular courses has been very close for many years. In Spain, for example, the two existing courses, in Madrid and Barcelona, were set up as part of a collaboration between the Spanish association (AMIFE) and universities in these two cities. Areas of common interest – CME/CPD, research, quality, etc. – would provide common ground for this collaboration that I feel is absolutely necessary in these times. IFAPP is very supportive of this initiative – as shown by funding the meeting held in Brussels on June 7 – and will delegate in CEPM's 'European Chapter' future activities and development. We will see the shape the proposed federation takes but I am confident that we will find ways to work together, IFAPP and the 'Faculty of Pharmaceutical Medicine', in promoting education in Pharmaceutical Medicine in Europe in a more efficacious fashion that we have been able to do it up until now.

*The 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians' in the UK endorsed the meeting and was represented by the Chairman of its International Committee, Dr. Ibrahim Farr. A summary of the meeting will be published in the next issue of IFAPP World in December 2007.* ■

## IFAPP's Executive Committee

IFAPP's last Executive Committee face-to-face meeting in Vienna in March 2007 reviewed achievements, analyzed the ongoing initiatives and discussed future plans. Delegates from 16 countries were involved, almost all of them snapped on a photo (persons from the left to the right):

*Jean-Paul Deslypere – Singapore, Gerfried Nell – Austria, Johanna Schenk – Germany, Montse Barcelo – Spain, Dimitris Michailidis – Greece, Domenico Criscuolo – Italy, Henri Pintens and Herman Lahon – both Belgium.*

*Rudolf van Olden – the Netherlands, Jean-Paul Deslypere, Sander Becker – Australia, Chris Allen – USA, Herman Lahon, Dimitris Michailidis, Gustavo Kesselring – Brazil, and Stewart Geary – Japan.*

*Jane Barrett – United Kingdom, Montse Barcelo, Norbert Clemens – President DGPharMed – Germany, Johanna Schenk, Henri Pintens, Helmut Schuh – President GPMed – Austria, and Gerfried Nell*

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*Pharmacovigilance*

## ◀ Risk Management Plans

Risk management planning has undergone a revolution since the development of the ICH[1] E2E Guideline on Pharmacovigilance Planning. Although the three major ICH regions – the EU, Japan and US – have all adopted the guideline, in practice companies in the three regions have very different requirements.

The EU requires submission of a Risk Management Plan (RMP) patterned after the E2E guidance with the addition of evaluation of a need for risk minimization activities whenever a Marketing Authorization Application is submitted for a New Chemical Entity or an application is made for a significant change in an existing marketing authorization, even if the RMP itself does not propose any activities beyond routine pharmacovigilance.

In contrast, current Japanese notifications interpret the E2E guideline under the existing Good Postmarketing Study Practice (GPSP) ordinance and therefore in most cases, the basic plan for postmarketing pharmacovigilance submitted by companies in Japan does not follow the format or content of the E2E guideline.

The situation in the United States of America continues to evolve with important upcoming legislation currently being debated in the US Congress that may require a plan for Risk Evaluation and Minimization Strategies (REMS) to be submitted with new drug applications. At the moment, in addition to the E2E guidance, the US Food and Drug Administration (FDA) has issued three guidances related to risk management and seems to favor an approach where highly targeted Risk Minimization Action Plans (RiskMAP) are used when a significant, preventable risk has been identified but does not require submission of an E2E-style document if nothing more than routine pharmacovigilance practices are being proposed.

*(1) ICH – International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (www.ich.org)*
*(2) CIOMS – Council for International Organizations of Medical Sciences (www.cioms.ch)*

As a result, companies are unlikely to ever be in the position to submit the same Risk Management Plan to the three ICH territories for the same chemical entity. Even in cases where a very targeted risk minimization plan is proposed, the realities of differences in medical and legal practice in the US, EU and Japan mandate that substantially different activities are proposed in the three regions. The movement to create risk management plans springs in part from a desire to move from "one size fits all" pharmacovigilance to tailored risk management or pharmacovigilance plans that are unique for a given drug, but in fact we are learning that even the plan for a single drug will not be "one size fits all" for the three ICH regions.

## Communicating New Safety Information to Clinical Trial Investigators

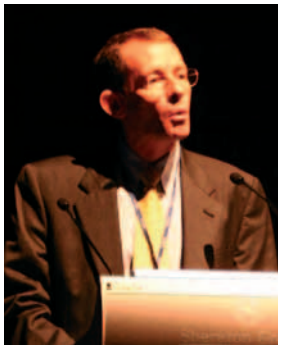
Another challenge to harmonized safety management arises during clinical development prior to approval. All countries expect that new and important safety issues are communicated to clinical trial investigators, but these expectations are codified in very different ways.

The FDA in the US requires companies to send individual reports of Suspected Unexpected Serious Adverse Reactions (SUSARs) to clinical trial investigators in the same format and timeline as are sent to the FDA and technically requires this for investigators participating in studies filed to an Investigational New Drug Application (IND) regardless of whether they are located in Florida or France.

The EU guidance on informing investigators of SUSARs allows reporting using cumulated line-listings of events rather than individual reports, but even within the EU some countries require that individual SUSAR reports are provided to investigators.

Japan also requires expedited provision of individual SUSAR reports to investigators, but the reporting requirements for which reports must be expedited differ from the US and EU.

As a result, there is no uniform standard that can be applied when a single trial is performed simultaneously in all three ICH regions. When sponsors default to the FDA requirement for expediting individual SUSARs to investigators, some investigators complain that they are overwhelmed by a large volume of reports, which are difficult to interpret. Under Good Clinical Practice (GCP) the investigator has the weighty responsibility to make trial-related medical decisions and up-to-date knowledge on the safety profile of the investigative drug is essential for fulfilling that responsibility, but



*Dr Stewart Geary, Japan, at his presentation on pharmacovigilance at ICPM2006 in Seoul*

investigators are justifiably frustrated by our current system, which requires large quantities of raw information to be sent to investigators without interpretation or context.

## Commentary

The real difficulty with harmonization is that despite the adoption of common guidelines through the ICH process the interpretation and application of those guidelines is different in each country. Those differences risk introducing the dissonances that disrupt the harmony of consistent global pharmacovigilance practices.

Best references for safety novices are the CIOMS[2] reports, especially CIOMS V for better understanding postmarketing pharmacovigilance and CIOMS VI for understanding safety management in clinical trials. ■

*IFAPP's Regional Update*

# New President in Hungary

*Hungary* • In February 2007 the Hungarian 'Clinical Trial Management Society' (CTMS respectively MKVT – Magyarországi Klinikai Vizsgálatszervezök Társasága), representing Pharmaceutical Medicine in Hungary, elected Dr Zoltán Hosszú as its new President.

Prof. Dr Sandor Kerpel-Fronius (CTMS/MKVT) serves as the new Hungarian delegate to the IFAPP 'Council for Education in Pharmaceutical Medicine' (CEPM).

# New President in Serbia

*Serbia* • In April 2007 the 'Serbian Association of Pharmaceutical Physicians' (SFM) elected Prof. Dr Milica Prostran as new SFM President. She is Professor of Pharmacology, Clinical Pharmacology and Toxicology at the School of Medicine at the University of Belgrade, Serbia. ■

*Reports & Concepts*

# Pharmaceutical Medicine Today and Tomorrow: an International Update

*Austria* • "Pharmaceutical Medicine today and tomorrow: an international update" was the title of a joint meeting of the Austrian 'Society for Pharmaceutical Medicine' (GPMed) and its sister organization the 'Clinical Trial Management Society' of Hungary (CTMS respectively MKVT – Magyarországi Klinikai Vizsgálatszervezök Társasága) in Vienna, Austria, on 4 December 2006. It was the first joint meeting of these two societies focusing on Pharmaceutical Medicine. The symposium key focus was to look across borders, envisaging the development of Pharmaceutical Medicine at an international level.

At the beginning of the symposium, both societies have introduced themselves. Then Professor Dr Sandor Kerpel-Fronius, representative of the Hungarian CTMS/MKVT, expanded on plans to establish a course in Pharmaceutical Medicine in Hungary, possibly in collaboration with neighboring countries.

*The famous „Fiaker" in Vienna (Photo: Gernot Huber)*

The international scope of Pharmaceutical Medicine then was introduced by Dr Johanna Schenk, DGPharMed, Germany, who gave a vivid overview of the ICPM 2006 highlights from Seoul, Korea. The symposium culminated with lectures by Dr Heide Rohde-Germann, SSPM, Switzerland, and Dr Jane Barrett, BrAPP, United Kingdom, describing Pharmaceutical Medicine continuing medical education (CME) and continuing professional development (CPD) in their respective countries. Switzerland and the United Kingdom were the first European countries to officially acknowledge this discipline as a medical specialty in its own right.

In the discussion which followed, speakers emphasized that Pharmaceutical Medicine is a well-defined medical specialty. However, the status of official recognition of CME and CPD widely varies, even in Europe. It was concluded that European countries should define common standards to allow for uniform high quality and international flexibility in the discipline of Pharmaceutical Medicine.

*Prof. Dr Gerfried Nell, Austria,*
*IFAPP delegate and President-Elect* ■

*IFAPP's Regional Update*

# Italian SSFA Launches Journal

*Italy* • The Italian 'Association of Pharmaceutical Medicine' (SSFA) recently launched its own bimonthly journal 'SSFA oggi' (SSFA today), which is mailed to all SSFA members.


SSFA *oggi*

The Council of SSFA (www.ssaf.it) is proud to announce the completion of the inaugural issue in May 2007. 'SSFA oggi' contains four pages with current news, interviews with key players in Pharmaceutical Medicine, and an agenda of forthcoming events. With SSFA oggi the SSFA Council intends to increase visibility and raise the profile of the SSFA while establishing an invaluable communication forum for all members. ■

*Dates & Deadlines*

**29 August –1 September 2007**
**• Amsterdam, the Netherlands**
**8th EACPT Congress –**
**European Association for Clinical Pharmacology and Therapeutics –**
**Patient-tailored Pharmacotherapy**

Please note the corresponding article on page 9.
www.eacpt2007.nl in the worldwide web.

**27-29 September 2007 • São Paulo, Brazil**
**4th Latin American Congress of Clinical Research –**
**Global Initiatives of Clinical Research in Latin America**

Please note the corresponding article on page 9.
www.sbmf.org.br in the worldwide web
program: www.sbmf.org.br/dia_2007/programa.pdf.

**19 October 2007 • London, United Kingdom**
**9th IFAPP European Conference –**
**Europe's Role in Clinical Research:**
**Challenges and Opportunities**

Please note the corresponding article on page 9.
www.ifapp.org – find the detailed program on page 13 of this issue.

**7-10 September 2008 • Amsterdam, the Netherlands**
**ICPM 2008 –**
**15th International Conference on Pharmaceutical Medicine**

Please note the article "ICPM 2008 in Amsterdam" on page 8.
www.icpm2008.org in the worldwide web.

*Reports & Concepts*

# Medical Writing in Pharmaceutical Medicine

A forum on "Medical Writing in Spain" was held in Madrid during the VII Meeting of the 'Spanish Association of Pharmaceutical Medicine' (AMIFE). Before starting the forum, three key questions were asked of the audience to promote discussion.

*First Question* • Do you prefer a medical writer, i.e., a physician or any writer of medical texts including people with other academic background? The most popular response: People prefer expert medical writing professionals, regardless of their background.

Medical writing has been defined here as writing scientific documentations by someone, who is a specialized medical writer, but generally is not one of the investigators involved in the research. The medical writer is a specialist in communicating scientific data from medical science or allied professions and sciences, thus he or she supplements the people who produce the data to create documents that effectively and clearly express the messages the data have to tell. The medical writer also serves to make sure that the documents comply with regulatory, journal or other guidelines in terms of content, format and structure. Therefore, the medical writer can be defined not only as a writer, but also as an advisor in scientific communication.

*Second Question* • Should the medical writer be a ghostwriter or a star writer? This question was focused on authorship in scientific articles and means: is the medical writer a person contracted to format results without any further implications? Or is he an expert that fosters the dissemination of results and, therefore, should sign as an author?

The most frequent response to these questions was that medical writing tasks in peer-reviewed manuscripts should be openly acknowledged in a way agreed between the medical writer and the contractor. Apart from signing as an author in the byline, other possibilities discussed were an acknowledgment placed at the end of the article in a particular section, or in a footnote in the first page of the article. At this point, the 'European Medical Writers Association' (EMWA; www.emwa.org) guidelines and statements on the role of medical writers in developing peer-reviewed publications were presented, and it was suggested that medical writers should be listed as authors only if they fulfill the criteria of the target journal, usually according to 'International Committee of Medical Journal Editors' (ICMJE; www.icmje.org) criteria but bearing in mind that, as an author, the medical writer takes on public responsibility for the research.

*Third Question* • What is about the central issue – quality control or disaster prevention? In other words, does the medical writer, as an expert professional, provide quality assurance in communication of results, or is the medical writer's function to improve results presentation by making them clear and effective? With regards to this question – in contrast to the two previous questions – the audience response was divided in two parties with an almost equal split. This revealed a perception of the medical writer as an expert that improves the quality of texts, figures and tables, but also as a key professional who increases the success rate in document revision and approval. The difference between poor- and high-quality medical writing may also constitute a difference between a speedy and a delayed submission and approval of a regulatory dossier or of a manuscript in a peer-reviewed journal.

*Dr Vicente Alfaro, Clinical R&D, PharmaMar, S.A., Barcelona, Spain*

*IFAPP's Regional Update*

# Medical Writing in Spain Gaining Ground

*Spain* • The forum on "Medical Writing in Spain", hosted by the Spanish 'Association of Pharmaceutical Medicine' (AMIFE) during its VII Meeting in Madrid, was moderated by Dr José Javier García, president of the Spanish 'Association of Contract Research Organizations' (AECIC). As he explained, medical writing today is the third top niche of clinical research organization's (CRO) services in Spain. In fact, the greatest increase in CROs revenues, more than 16% in 2006, resulted from medical writing services – the most frequently used were protocol writing (89%), writing final study reports (75%), preparing manuscripts for peer-reviewed journals (75%) and posters for scientific meetings (69%). These data correspond well with various other surveys in this field and suggest that documentation in Pharmaceutical Medicine constitute the most valuable services in medical writing worldwide.

In the past, medical writing has been an underappreciated field in the Spanish pharmaceutical industry, but more recently it has gained attention by sponsor companies as an important tool in drug development and marketing. Moreover, since 2004, the current national legislation in Spain states that the sponsor is obliged to publish clinical trial results, whether positive or negative. This new legislation has likely increased the demand for medical writer services.

Most medical writers working in Spain are freelance or based in CROs rather than in pharmaceutical companies, with only few of them qualified physicians. Scant information on medical writing is available at the Spanish national level. During the AMIFE forum, the role of associations such as the 'European Medical Writers Association' (EMWA) or the recently created 'Spanish Medical Writers Association (AERTeM, www.redactoresmedicos.com) and their training programs for medical writing professionals in English such as the 'EMWA Professional Development Program' and in Spanish was emphasized.

*Dr Vicente Alfaro,*
*Clinical R&D, PharmaMar, S.A.,*
*Barcelona, Spain*

*Members of the Board of Directors of the Spanish 'Association of Pharmaceutical Medicine' (AMIFE) with AMIFE President Dr Jorge Gonzalez Esteban at the head of the table (5th from left) and AMIFE Delegate to IFAPP Dr José Maria Giménez Arnau (2nd from left) enjoying the gala dinner during AMIFE's VII Meeting 2007 in Madrid, Spain. (Photo: Marta Llorens, TFS Trial Form Support, Spain)*

*IFAPP's Regional Update*

# BrAPP is 50

*United Kingdom* • On 8 March 1957, ten doctors working in the newly developing pharmaceutical industry joined together in London to discuss the establishment of a group for like-minded and like-qualified individuals who could meet and discuss issues around Pharmaceutical Medicine, a term yet to be coined.

This small forward thinking group decided to form the 'Association of Medical Advisers to the Pharmaceutical Industry' (AMAPI) as an independent organization, which then met for the first time on 30 October 1957. Members could be any medical graduates employed by the industry in an advisory capacity; at that time consultants were not included in the membership. The initial plan was for AMAPI to be an exclusive association only allowing medically qualified individuals from the United Kingdom (UK) to join. The early committee members were careful to ensure that both the 'British Medical Association' and the 'Association of British Pharmaceutical Industries' were regularly appraised of their intentions and to keep all activities transparent and inclusive.

Once established, AMAPI maintained regular meetings and its membership grew throughout the 60's and early 70's. Working in industry at that time was as challenging as it is today, the 1968 Medicines Act and ramifications of the thalidomide crisis made the role of physicians, whose primary aim was the welfare of patients, vitally important to its commercial success. In April 1972, AMAPI organized the "International Meeting of Medical Advisers in the Pharmaceutical Industry", an outstanding success with 600 physicians participating from 36 countries. Out of this meeting IFAPP was formed in 1975.

During the 70's, AMAPI worked with the Department of Pharmacy at the University of Wales in Cardiff, UK, to develop the world's first postgraduate course in Pharmaceutical Medicine, launched in 1976. During the 80's, the AMAPI committee formulated ideas for the inception of a 'Faculty of Pharmaceutical Medicine' (FPM) – re-named the 'British Association of Pharmaceutical Physicians' (BrAPP) in 1986; the association was instrumental in its inauguration in 1989.

Aiming to respond to the BrAPP membership needs and being actively involved in advising new recruits or physicians throughout their careers are key goals. BrAPP organizes regular meetings and training courses for members and non-members. These are opportunities for networking and discourse, which are vital for the practice of Pharmaceutical Medicine. BrAPP welcomes overseas members, i.e., physicians not based in the UK, and honorary membership is offered to individuals who have made an outstanding contribution to the Association. However, BrAPP remains an exclusively medical organization. Their journal entitled 'Pharmaceutical Physician' is published six times a year and attracts readers and authors from across the world. BrAPP membership looks forward to their next 50 years with great enthusiasm.

*Dr Michael E Telford, Chairman of BrAPP* ■

*IFAPP's Regional Update*

# NVFG Celebrates 45th Anniversary

*The Netherlands* • The 'Netherlands Association of Pharmaceutical Physicians' (NVFG) is going to celebrate its 45th anniversary with the "Lustrum Symposium on Innovation." The exciting event will take place on 6 September 2007 in the Evoluon, an innovative venue in the city of Eindhoven, the Netherlands. During the date, prominent speakers will give their vision on innovation based on their daily practice. In the evening, an informal dinner will follow featuring a program of music and dance from 45 years ago to modern times. NVFG members and non-members are welcome to attend the symposium and dinner, which promise to be a memorable event.

For further information please visit the web site www.nvfg.nl. In the next issue of IFAPP World we will provide a summary of the symposium with photographic coverage of this important day.

*The Evoluon (www.evoluon.org) in Eindhoven, the Netherlands, gives the impression that a flying saucer has just landed. Built in 1966 to house Eindhoven's museum of science and technology it was transformed into a conference center when the original concept began to run out of steam. However, today, more than 40 years later, it still appeals to the imagination.* ■

*IFAPP's Calendar*

# 'ICPM 2008' in Amsterdam

## Developing Pharmaceutical Care – Medicines After the Blockbuster Area

In preparation for ICPM 2008 – the '15th International Conference on Pharmaceutical Medicine' – 7-10 September 2008 in Amsterdam, the Netherlands – IFAPP President, Dr Luis F. Collia, visited the local organizing committee on 28 March 2007 to verify current progress.

This meeting took place in the Okura Hotel Amsterdam, the venue of the ICPM 2008. Dr Collia was impressed by the work, which has been achieved so far. The first draft of the program is already available and potential sponsors have been alerted to this unique meeting. More information can be found on the website www.icpm2008.org where you also might subscribe to the ICPM 2008 Newsletter or just download the May 2007 issue of this newsletter which contains a draft program.

*Please put an ICPM mark in your 2008 calendar now.*

*Dr Rudolf van Olden (Chairman of the 'Netherlands Association of Pharmaceutical Physicians' – NVFG and Chairperson of ICPM 2008), Dr Luis F. Collia (IFAPP President), Dr Paul van Meurs (Secretary ICPM 2008) – from left to right.* ■

*IFAPP's 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."

*IFAPP's Calendar*

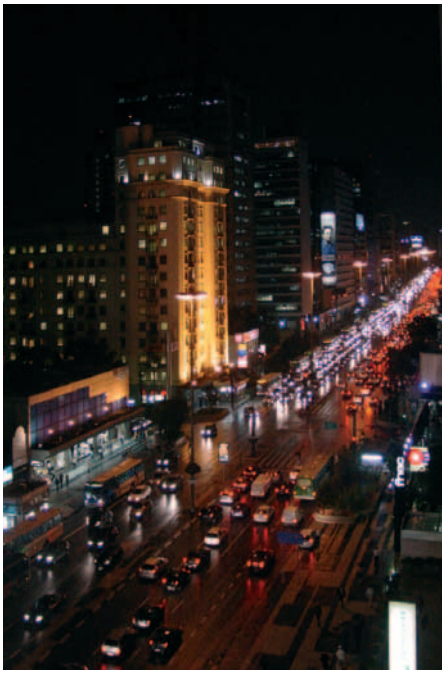
# Patient-tailored Pharmacotherapy

**8th EACPT Congress**
**• 29 August – 1 September 2007**
**• Amsterdam, the Netherlands**

At this event the 'European Association for Clinical Pharmacology and Therapeutics' (EACPT) provides professional and educational information on clinical pharmacology and patient tailored pharmacotherapy.

In collaboration with IFAPP, EACPT will hold a special afternoon session on Thursday, 30 August 2007, focusing on Clinical Research in Europe after the EU Directive. Keynote speakers on ethical reviews, clinical operations and modern trial design as well as audits and regulations are confirmed. The future of investigator-initiated trials (IITs) and experience with competent authorities and ethics committees will also be discussed.

*Built at the waters – Amsterdam, the Netherlands*



*Booming metropolis – São Paulo, Brazil (Photo: Alexandre Caliman)*

An IFAPP Satellite Session will address the key role of Pharmaceutical Medicine in providing answers to the questions: What is the link between clinical pharmacology and Pharmaceutical Medicine? What is the role of the Faculty and the IFAPP 'Council for Education in Pharmaceutical Medicine' (CEPM)?

*Full information is available at www.eacpt2007.nl* ■

# Latin America's Global Initiatives in Clinical Research

**4th Latin American Congress of Clinical Research**
**• 27-29 September 2007**
**• São Paulo, Brazil**

This congress will be of interest to all research and regulatory professionals. The program will offer a one-day advanced level pre-congress training course entitled "Good Clinical Practices for the Clinical Research Professional." In addition, there will be a two–day conference with presentations ranging from global topics to specific details in clinical research including ICH, FDA, and EMEA updates, Latin American regulatory guidelines and ethical issues, infrastructure and components of clinical research, perspectives and comparisons of emerging clinical research markets in Latin America, perspectives on professional development in clinical research as well as examples of translational research going from basics to public health interest. Simultaneous translation will be available in Portuguese, English, and Spanish.

*IFAPP speakers* • Featured speakers include several IFAPP representatives: IFAPP President Dr Luis Francisco Collia from SAMEFA, Argentina, IFAPP President-Elect, Professor Dr Gerfried Nell from GPMed, Austria, Dr Gustavo Kesselring, SBMF, Brazil, Dr Domenico Criscuolo, SSFA, Italy, and Dr. Johanna Schenk, DGPharMed, Germany.

*Other speakers* • Other speakers are e.g., Dr David A. Lepay of the US Food and Drug Administration (FDA), Professor Dr Helder Mota Filipe, Vice President of the National Institute of Pharmacy and Medicines (INFARMED), Portugal, Board Member of the European Medicines Agency (EMEA), Dr Luisa Lina Villa, Branch Director of the Ludwig Institute for Cancer Research, Brazil.

*Further information can be found at www.sbmf.org.br; the program is available at www.sbmf.org.br/dia_2007/programa.pdf* ■

# Europe's Role in Clinical Research: Challenges and Opportunities

**9th IFAPP European Conference**
**• 19 October 2007**
**• London, United Kingdom**

IFAPP is pleased to announce its 9th European Conference. It will cover two relevant topics entitled "The Impact of the EU Directive on Clinical Trials" and "The Emerging Role of Europe in Paediatric Development." IFAPP's Scientific Committee believes that these two issues will require a full day debate, with contributions from both Europe and the USA, as well as from speakers representing EMEA, academia and industry. Clearly this conference will be very fruitful and productive for all interested parties focused on such vital issues.

IFAPP has launched its first European Conference in 1997. Since then, IFAPP has an international event approximately every 15 months to discuss the most relevant issues in Pharmaceutical Medicine. In the past events a selected group of experts from Europe, USA, Latin America and Asia has addressed topics like drug safety, biotechnology products, elderly patients and globalization of clinical development. The discussions have always been animated and rewarding, with significant contributions from Regulatory, Academia and Industry Speakers.

*For more details visit www.ifapp.org; the detailed program is placed on page 13 of this IFAPP World issue.* ■

*The Tower Bridge, symbol of London, United Kingdom (Photo: Richard Styles)*

*Beyond the Horizon*

# Abridged Reports from ICPM 2006

**– Seoul, Korea, 3-6 September 2006 –**

## Report on Session G
## Biomarker in Drug Development

*Chair: Marleen Verlinden (USA), Sang Goo Shin (Korea). Speakers: Arthur Atkinson (USA): Biomarkers and Surrogate Endpoints: For What Purposes Are They Fit?; Howard Lee (USA): New Biomarkers in Clinical Development; Myeong-Hee Yu (Korea): Biomarker Research in Korea: Proteomics Approach.*

### Biomarkers and Surrogate Endpoints: For What Purposes Are They Fit?

Biomarkers and surrogate endpoints have the potential to streamline clinical development. However Dr Arthur Atkinson said, that in order to clearly understand the world of biomarkers, we need to align the terminology used. He suggested using biological marker and surrogate endpoints as potential terms. Currently, the use of 'surrogate marker' is discouraged because it suggests that the substitution is for a marker rather than a clinical endpoint. Atkinson gave us some examples of physiologic and laboratory endpoints. The only two surrogate endpoints used as a basis for drug approval are blood pressure and serum cholesterol level. Yet patient targeting biomarkers are now a standard of care including: as efficacy biomarker over-expression of HER2 in breast cancer, and as toxicity biomarker the non-functional thiopurine methyltransferase allel in thiopurine therapy. Following the US 'Food and Drug Administration's' (FDA's) Critical Path Initiative, biomarker use was discussed during the different stages in drug development. Serum cholesterol and QTc were used as examples for respective survival and torsade de pointes. The current needs in biomarker development are: 1. natural history studies to identify new candidate biomarkers, 2. development of safety biomarkers (liver toxicity and heart rhythm abnormalities), 3. patient targeting biomarkers developed in tandem with new therapeutic agents, and 4. increased application of new imaging technologies.

### New Biomarkers in Clinical Development

As Dr Howard Lee recalled, biomarkers were used in three different fields of clinical practice: as a diagnostic, therapeutic or prognostic tool. Biomarkers were used in drug development for faster, more efficient and better decision making. Surrogate endpoints in particular could have a huge regulatory implication. Additionally, it is important to realize that all surrogate endpoints are biomarkers, but not all biomarkers are surrogate endpoints. Based on the Critical Path Initiative, the FDA noted that the two most important areas in improving medical product development are biomarker development and streamlining clinical trials. However, most new biomarkers are discovered in an academic laboratory with only small clinical series results published in their support. Furthermore, the evidence base for regular use of a biomarker frequently remains controversial and is not adopted for regulatory use because of low supporting evidence. To summarize: a biomarker is a valuable toolkit for faster, better, and more efficient decision-making in drug development, the regulatory drive for better qualified biomarkers will continue, but the philosophical and methodological ground for biomarker development needs to be revisited.

### Biomarker Research in Korea: Proteomics Approach

The last speaker, Dr Myeong-Hee Yu, described the proteome analysis technology. The main analytical challenge is sample complexity. Compared to the static gene area, the area of proteins is much more dynamic and very complex. An overview was given of differential proteomics and even sub-proteomics: glycol- and phosphor-capture, organelle proteomic, secretomics and peptidomics. Dr Yu showed the protein biomarker discovery in the Korean Functional Proteomics Center. The recent work of the breast cancer biomarker discovery team was discussed with all the possibilities of translational research. He showed the different patient results distribution of classical cancer markers related to new, recently developed biomarkers. Based on their work with the tissue bank, they started a plasma-serum project platform to do further research with multiplex panel biomarkers, hoping to find new pathways and disease mechanisms.

*Dr Rudolf van Olden, member of the IFAPP Executive Committee, the Netherlands*

*Dr Rudolf van Olden, IFAPP Executive Committee member from the Netherlands, inviting to ICPM 2008 in Amsterdam*

*ICPM 2006 attendees in Seoul, Korea – the 'Land of Morning Calm' has changed to 'Dynamic Korea'.*

*Beyond the Horizon*

Report on Session 4

# Qualification of Clinical Research Professionals

*Chair: Cheong, Yuet-Meng (Asia). Co-chair: Hyung Keun Roh (Korea). Speakers: Chris Allen (USA): Certification of Physicians and Non-physicians in the US; Mirela Barbu (Switzerland): Training and Certification Program "Clinical Research Investigator"; Luís F. Collia (Argentina): Postgraduate Courses and Certification on Pharmaceutical Medicine in Latin America*


*Professor Juhana E. Idänpään-Heikkilä, CIOMS, Switzerland, at the Opening Lecture 'Beyond the Horizon'*

## Certification of Physicians and Non-physicians in the US

The first speaker, Dr Chris Allen, explained that in the US two associations offer certification for clinical research professionals: the 'Academy of Pharmaceutical Physicians and Investigators' (APPI) and the 'Association of Clinical Research Professionals' (ACRP). The aim of APPI is to enhance the proficiency of pharmaceutical physicians and physician investigators through the acquisition and dissemination of knowledge about the therapeutic action, investigation and development of medicines, devices and diagnostics, as well as the protection of the welfare of patients and study subjects. The purpose of ACRP is to provide leadership in promoting integrity and excellence for the clinical research profession.

Fourteen years ago, APPI was established inside pharma. The first members were physicians working in the pharmaceutical industry, in contract research organizations (CROs) and consulting companies or organizations as the US 'Food and Drug Administration' (FDA). Recently, a large number of physicians joined APPI. These new members are involved in clinical research with emphasis on pharmaceutical medicine, drug development, highest standards and ethics in clinical research.

The older organization is ACRP, which was founded 30 years ago. ACRP members include all professionals involved in clinical research. In the last six years ACRP membership significantly increased and reached the mark of 22,000 members in 2005. ACRP members work in the government, in the industry, academia, or in small companies and focus on education and certification of the entire clinical research team.

In 2005 APPI and ACRP joined efforts in order to improve their ability to impact public policy and standards, processes and ethics in clinical research. Together APPI and ACRP offer a combined certification course for the 'Certified Physician Investigator' (CPI) examination. Benefits of CPI certification include higher recognition by the global clinical research community, identification of standards for professional practice, professional satisfaction and growing support by a number of pharmaceutical companies and CROs that encourage certification.

## The 'Clinical Research Investigator' in Switzerland

The second speaker, Dr Mirela Barbu, described the training and certification program 'Clinical Research Investigator' that is currently being implemented in Switzerland. Dr Barbu pointed out that the Swiss law on therapeutic products and the ordinance on clinical studies explicitly require that investigators qualify for clinical research and document their training and experience. Three physician societies (Clinical Pharmacology and Toxicology, Pharmaceutical Medicine, and Social and Preventive Medicine) have taken the lead to set up the clinical investigator certification program. This program aims to ensure the provision of essential knowledge and skills to all physicians involved in the organization, execution and interpretation of clinical studies, involving investigators from universities, peripheral hospitals, policlinics and private practices. The content of the program is directed to provide knowledge and demonstrate experience of the ethical principles, scientific-methodological requirements, legal regulations, standards of Good Clinical Practice (GCP), as well as the practical organization and management of clinical studies. A commission was set up to organize the certification and acknowledge the training curricula. Certification will be implemented by the Swiss Medical Association during 2007.

## Pharmaceutical Medicine in Latin America

The third speaker, Dr Luis F. Collia, lectured on Postgraduate Courses and Certification in Pharmaceutical Medicine (PM) in Latin America. His presentation focused on the three countries affiliated to IFAPP: Argentina, Brazil and Mexico.

The 'Argentinean Society of Pharmaceutical Medicine' ('La Sociedad Argentina de Medicina Farmacéutica' – SAMEFA) was founded in 1970 and currently lists 90 members. In Argentina, the PM course is offered by the National Faculty of Medicine of the University of Buenos Aires and is expected to be recognized as a postgraduate specialist course in Pharmaceutical Medicine in 2007. Medical doctors (MDs) only are allowed to enroll for the two-year course that consists of 420 theoretical and 300 practical hours. The course curriculum is in accordance with the IFAPP syllabus. Regarding clinical research professional (CRP) training courses, there are two master degree programs that accept MDs and other health professionals: one in 'Clinical Investigation and Pharmacology' at

the Austral University, and the other in 'Clinical Pharmacology Investigation' at the Interamerican Open University.

The 'Brazilian Society of Pharmaceutical Medicine' ('Sociedade Brasileira de Medicina Farmacêutica' – SBMF) was founded in 1972 and currently has 96 members. In Brazil the official PM course is taught at the Federal University of São Paulo. The two-year course adapted its curriculum to meet IFAPP's syllabus and comprises 360 theoretical and 100 practical hours. It is open to MDs and graduates in other fields of medical sciences. Concerning CRP training courses, there is an independent course organized by a private company ('Invitare') and two postgraduate courses starting in 2007: one at the 'University of São Paulo' and another at the 'Santa Casa School of Medicine' in São Paulo.

The 'Mexican Pharmaceutical Physicians Association' ('Asociación de Médicos Especialistas en la Industria Farmacéutica' – AMEIFAC) was established in 1967 and today has 100 members. In Mexico, the PM course is organized by the Polytechnic Institute in Mexico City and is recognized by the 'Superior School of Medicine'. It is open to MDs and graduates of other fields of medical sciences. The total teaching time of this two-year course is 480 hours and includes theoretical and practical teaching time. This course is under evaluation for IFAPP accreditation. With regards to CRP training, there are three master degree courses in Mexico: at the 'National Polytechnic Institute', at the National Autonomous University of Mexico, and at the Autonomous University of Nuevo Leon; however, none with official certification.

*Dr Gustavo Kesselring, member of the IFAPP Executive Committee, Brazil*

## Report on Session J
## Pharmacogenomics

*Chair: Ronald Krall (USA). Co-chair: Jae-Gook Shin (Korea). Speakers: Allen Roses (USA): Drug Development with Pharmacogenetics; Yoshiaki Uyama (Japan): J-2 Regulatory Perspective to use Pharmacogenomics in Clinical Drug Development and Future Direction of Pharmaogenimics*

ICPM 2006 ended with a session on pharmacogenomics (PG), as a message underlining that the future of Pharmaceutical Medicine is closely linked to this new discipline.

The first speaker, Dr Allen Roses, focused on PG in clinical development, making the point that PG data are more frequently published, and underlining the fact that PG is emerging as a new regulatory tool for a better definition of the benefit/risk ratio. He also reported data from the PRESTO trial, where patients who developed hyperbilirubinemia were linked to seven well identified polymorphisms. PG is beginning to be identified as an important tool to stratify patients, with fewer patients needed in order to isolate PG subgroups at risk of adverse drug reaction (ADRs).

The second speaker, Dr Yoshiaki Uyama from the Japanese 'Pharmaceutical and Medical Device Agency', suggested that the future approach to clinical trials will be first to run a genetic analysis at screen, and then to randomize patients, in order to create comparable groups of patients. He also highlighted that Japan is keen to start promoting clinical trials with PG testing: he reported that the Japanese Ministry of Health, Labor and Welfare issued a guideline for the PG testing in clinical trials in 2005, and that a task force was formed to better address this complex issue. Also the 'International Conference on Harmonization' (ICH) is taking action in this area and established the ICH E15 working group in April 2006; its task will be to make suggestions and recommendations for PG testing in clinical trials.

Finally, as possible goals for 2010 to 2015, Dr Uyama identified more intense use of PG data and a move towards personalized medicines. A potential future scenario may be a PG package in new drug applications (NDAs) and the development of ID cards with genetic data.

*Dr Domenico Criscuolo, member of the IFAPP Executive Committee, Italy*


*Korean-Style Entertainment at the Gala Dinner at ICPM 2006 in Seoul, Korea*

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 30 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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International Federation of Associations
of Pharmaceutical Physicians
*founded 1975*

# THE NINTH IFAPP EUROPEAN CONFERENCE

London, Friday 19th October 2007

# Europe's Role in Clinical Research: Challenges and Opportunities

*In collaboration with the*
*British Association of Pharmaceutical Physicians*
*(BrAPP)*

Hilton Docklands Hotel
265, Rotherhithe Street • SE16 1EJ London
Phone +44 207 231 1001 • Fax +44 207 231 0599

| • CPD Credits |
|---|
| This conference will be awarded with CPD credits from the Faculty of Pharmaceutical Medicine of the Royal Colleges of the United Kingdom |

| • Scientific Committee | |
|---|---|
| Dr Jane Barrett | Dr Domenico Criscuolo |
| Dr Luis F. Collia | Prof Dr Gerfried Nell |

# • Programme

| | | | |
|---|---|---|---|
| 08h 15 - 08h 45 | • Registration | | |
| 08h 45 - 09h 00 | • Introductory Remarks | *Domenico Criscuolo* | *IFAPP* |
| | **• Morning Session**<br>**The Impact of the EU Directive on Clinical Trials** | | |
| | *Chairs: Trevor T. Hansel (NHLI) and Domenico Criscuolo (IFAPP)* | | |
| 09h 00 | **The Status of Directive Implementation** | *Fergus Sweeney* | *EMEA* |
| 09h 30 | **Opportunities and Threats from the EU Directive** | *Magnus Jaderberg* | *Wyeth Europe* |
| 10h 00 | **Implications of the Clinical Trial Directive on Respiratory Clinical Pharmacology** | *Trevor T. Hansel* | *National Heart and Lung Institute* |
| 10h 30 | • Coffee | | |
| 11h 00 | **Clinical Trials Directive: Quo Vadis?** | *Ingrid Klingmann* | *Pharmaplex* |
| 11h 30 | **The Role of Europe in Drug Development** | *To be announced* | *EFPIA* |
| 12h 00 | **Discussion** | | |
| 12h 30 | • Lunch | | |
| | **• Afternoon Session**<br>**The Emerging Role of Europe in Paediatric Development** | | |
| | *Chairs: Jane Barrett (BrAPP) and Agnès Saint Raymond (EMEA)* | | |
| 13h 30 | **The New EU Regulation on Paediatric Drug Development** | *Agnès Saint Raymond* | *EMEA* |
| 14h 00 | **EU Paediatric Regulation: Strategic Challenges and Opportunities for the Industry** | *Klaus Rose* | *Roche* |
| 14h 30 | **The Perspective and Experience of the USA** | *Ronald E. Keeney* | *INC Research* |
| 15h 00 | **Linking Clinical Trials and Therapeutic Needs: a New Chance of Developing Better Medicines for Children** | *Adriana Ceci* | *University of Pavia* |
| 15h 30 | **Discussion** | | |
| 16h 00 | **Concluding Remarks and End of Meeting** | *Agnès Saint Raymond*<br>*Jane Barrett* | *EMEA*<br>*BrAPP* |


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## • Contents of the Conference

The globalisation of clinical research has significantly changed the usual scenarios of drug development. Not only new countries like the Eastern European ones, but also new geographic regions like Asia have established in a short period of time good infrastructures and networks of qualified investigators to compete for the global market of clinical trials. CROs – which are very sensible to these opportunities – are driving this shift. Europe has to accept this challenge and must concentrate on several 'Cen-tres of Excellence' in order to maintain a leading role in drug development. In this respect, the fruitful collaboration pro-vided by EMEA is certainly a significant asset.

## • Target Audience

The conference is addressed to pharma-ceutical physicians: in addition all pro-fessionals involved in clinical research, regulatory affairs, drug safety as well as regulators and clinical investigators, and all those involved in the development of medicinal products, will benefit from this up-to-date review of opportunities which are arising in Europe.

## • Language

The conference language is English.

## • Conference Venue

The conference will take place at:

Hilton Docklands Hotel
265, Rotherhithe Street
SE16 1EJ London

Phone +44 207 231 1001
Fax +44 207 231 0599

For your information please note that London City Airport is the closest one.

If you want IFAPP to reserve your hotel accommodation, please complete the en-closed hotel reservation form and return it to the IFAPP secretariat as soon as possible. We reserve a number of rooms for attendees until 31 August 2007.

## • Certificate of Attendance

The IFAPP will grant a Certificate of At-tendance to all delegates. The confe-rence will be awarded with CPD (Conti-nuing Professional Development) credits from the Faculty of Pharmaceutical Medicine of the Royal Colleges of the United Kingdom.

## • Registration Fee

You can register for this conference by filling in the enclosed registration form and returning it to the IFAPP secretariat. Registrations will be accepted only upon receipt of payment.

The registration fee is **EUR 800.00**
For BrAPP members **EUR 700.00**

You should pay the registration fee by bank transfer to:

Account no. 55.84.60.739
ABN AMRO BANK
P.O. Box 2
3640 AA MIJDRECHT
The Netherlands
BIC: ABNANL2A
IBAN: NL30ABNA0558460739

## • Lunches and Coffee Breaks

Coffee and lunch are included in the registration fee.

## • Confirmation

After receipt of your registration form you will receive a confirmation and an invoice.

## • Cancellation

In the event of cancellation on or before **17 September 2007** the fee will be re-imbursed by deduction of a 20% (EUR 160.00 respectively EUR 140.00) admini-stration fee.

In case of cancellation after 17 Septem-ber 2007 there will be no reimbursement on the registration fee.

Replacement of a delegate can occur at any time without additional charge.

## • Hotel Accommodation

On the enclosed hotel reservation form you will find information about several hotels. If you want us to reserve your hotel accommodation, please mention your hotel preference.

## • Further Information

For further information please contact:

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