IFAPP WORLD
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International Federation of Associations of Pharmaceutical Physicians
I·2007·APRIL

CONTENT

President's Letter

Dear Colleagues

Dr Luis F. Collia, IFAPP President

More than 30 years after its foundation IFAPP is no longer a virtual federation but an officially registered body.

During December we completed the new IFAPP Constitution according to the motion and applied an official registration as a non-profit organization in the Netherlands. On 22 March 2007 the 'Kamer van Koophandel' in Utrecht eventually registered IFAPP under the dossier number 30224375 and the address of the IFAPP Secretariat in Rendementsweg 24 E-I, 3641SL Mijdrecht, the Netherlands. This should facilitate delivering on the IFAPP mission and vision at an international level.

With regards to the motion made by DGPharMed, Germany, concerning 'Weighted Voting Rights for IFAPP's Member Associations,' I also want to notify you that two thirds of the Member Associations voted in favor of the amended IFAPP Constitution – so it was considered approved. For details please refer to page 4 in this issue.

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IFAPP's Calendar

'ICPM 2008' in Amsterdam

Developing Pharmaceutical Care – Medicines After the Blockbuster Area

Preparations for ICPM 2008 – the '15th International Conference on Pharmaceutical Medicine' – 7-10 September 2008 in Amsterdam, the Netherlands, are in full swing! One team is focusing on content while another is concentrating on logistics.

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The 'Kingdom of the Netherlands' on the north western end of Europe, squeezed in between the North Sea, Belgium and Germany, is famous for their cultivation of flowers, their production of big wheels of cheese and their traditional wooden shoes. Some people still wear traditional wooden shoes, however, their wearers likely work in the tourism and entertainment industry.

Questions & Answers

Shortfall of Qualified Persons in Pharmaceutical Medicine

Dr Norbert Clemens (right, with Eckhard Böttcher-Bühler): "The qualified persons shortfall is a phenomenon, which indeed is found in many countries…"

The concept of Pharmaceutical Medicine and its role in research and development is discussed with Dr Norbert Clemens, MD, President of the 'German Society of Pharmaceutical Medicine' (DGPharMed – Deutsche Gesellschaft für Pharmazeutische Medizin) – questions were raised by Eckhard Boettcher-Buehler.

The pharmaceutical industry worldwide invests a tremendous amount of money in research and development (R&D) of new drug applications (NDAs) with remarkably high growth rates. Recently the US 'Government Accountability Office' (GAO) reported an increase of US drug industry R&D expenditures within the decade from 1993 to 2004 – inflation-adjusted – from 16 to 40 billion US $ – "a 147% increase." However, during the same time period the number of NDAs submitted to the US 'Food and Drug Administration' (FDA) increased by only 38% and more than two-thirds of these NDAs were classified as modifications to existing drugs. Similar trends are seen in Europe with many other countries and experts already highlighting this as worldwide pharmaceutical R&D crisis.

There are multiple reasons behind it, but a main cause is the constant increase in standards required by the authorities.

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President's Letter

As you may already know, the IFAPP Executive Committee and the House of Delegates unanimously accepted a new national Member Association, Singapore, as the 30th IFAPP Member with Professor Dr Jean-Paul Deslypere as its official delegate to IFAPP and member of the IFAPP Executive Committee. Congratulations! I also would like to congratulate the newly elected Presidents of the national Member Associations from Argentina, Australia, Finland, Germany and Turkey.

To remind us of the interesting issues and great times at ICPM 2006 in Seoul, Korea, we would like to present one further short report from Seoul, which you may find on page 7. You also are invited to review all the material from the different sessions and lectures on our website at www.ifapp.org – following the menu 'news', 'latest news' and 'archive' you will find a corresponding list within 'December 2006'. With regard to IFAPP's scientific activities, I would like to remind you of three relevant arrangements:

First: The EACPT-IFAPP Symposium titled 'Clinical Research in the EU after the EU Directive' which is scheduled for 30 August 2007 as an integral component of the '8th Congress of the European Association for Clinical Pharmacology and Therapeutics' in Amsterdam, the Netherlands. You will find detailed information on the website www.eacpt2007.nl.

Second: With regard to the projected EMEA-IFAPP Conference, the Organizing Committee of IFAPP and EMEA is working on the program and searching for an adequate and appealing venue close to EMEA's headquarters in Canary Wharf, London, UK.

Third: Remember the date: ICPM 2008, 7-10 September 2008 in Amsterdam, the Netherlands. 'Developing Pharmaceutical Care: Medicines after the blockbuster era' is the main focus. Dr Rudolf van Olden, member of the IFAPP Executive Committee and IFAPP's 'Council for Education in Pharmaceutical Medicine' (CEPM), and President of the 'Netherlands Association of Pharmaceutical Physicians', is proceeding with the organization of this event. Take a look at the website for the latest news and register for the related newsletter: www.icpm2008.org

Last but not least: I kindly invite you all to work with the Executive Committee of IFAPP on regional and international needs and concerns in order to meet IFAPP's objectives and achieve the recognition and visibility that we are seeking.

Thank you all for your active participation in IFAPP's operations.

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

Questions & Answers

Consequently, not only will costs for R&D increase, but also the number of experts in Pharmaceutical Medicine who are needed to meet all the requirements. However, they are becoming more difficult to find.

IFAPP WORLD: Dr Clemens, in your position statement from early 2007 you pointed out that the industry's unmet demands for experts in Pharmaceutical Medicine already has become a challenge for the German business location. Is this deficit apparent just in Germany or do we share it with other countries?

Dr. Clemens: The qualified persons shortfall, in particular the shortfall of clinical trial investigators, is a phenomenon, which indeed is found in other countries. However, regarding the particular infrastructure of the health care system, generally hospitals and academic teaching, training and treating aspects, it is more pronounced in Germany.

German pharmaceutical industry R&D expenditures increased 33% from 3 to 4 billion Euro from 2000 to 2005. In the same time the number of qualified staff members grew by only 5%. The demand on qualified study sites has increased during the past number of years due to raised standards and requirements.

IFAPP WORLD: You are President of the 'German Society of Pharmaceutical Medicine' – DGPharMed. What action is the DGPharMed taking to address the lack of qualified workers?

Dr. Clemens: The DGPharMed provides its members a substantial program for continuing education and training, which is designed by the according DGPharMed commission. In recent years CME certificated seminars have been added, which qualify clinical trial investigators. Certainly drug development is based on the specialized knowledge of such experts, but they also need to receive adequate recognition within their hospitals.

IFAPP WORLD: In principle: is this education and training an issue for just the pharmaceutical industry and does it qualify the DGPharMed simply as an instrument of this industry?

Dr. Clemens: Continuing education and training for the qualification of specialized staff is of wide interest to all parties involved in public health; not just in Germany but in all nations worldwide. We don't see us as an instrument of the pharmaceutical industry, but rather we are servants of the medical community and the society overall providing expedient qualification to all members of the DGPharMed who are working in drug development and clinical research.

IFAPP WORLD: It's somewhat political. What are politicians and the community doing to resolve this scarcity of qualified personnel? After all, have they caused the increasing demand by the increasing desire for safety – even the directives and laws require the 'qualified person.'

Dr. Clemens: That's right. Legal stipulations constantly rise and there is no end in sight. However, politicians and the community award only marginal promotions and grants to qualify the personnel accordingly, while pharmaceutical industry expenditures are vast. For instance, there just is the so called CLEAR project, which stands for 'Clinical Research Physician', an EU postgraduate training program financially supported by the European Commission – after all it is a political signal and a reaction to the challenges of the European business location.

IFAPP WORLD: Recently German universities have launched courses to qualify in 'Master of Science in Pharmaceutical Medicine' and 'Master of Science in Clinical Research.' Does this compete or supplement the DGPharMed courses and do the organizers cooperate?

Dr. Clemens: The DGPharMed neither is an academic institution nor a host for commercial seminars. That is why we perceive these university courses as a reasonable contribution to qualify persons. We do not compete with it.

IFAPP WORLD: Yet a 'Master of Science in Pharmaceutical Medicine' is not what the DGPharMed and the IFAPP actually strive for, correct? They appear to prefer the 'Physician in Pharmaceutical Medicine', which is a distinct specialty in academic medicine. What exactly is the difference between the two degrees?

Dr. Clemens: The 'Master of Science' is available to all who meet the general requirements, while only physicians can be recognized as medical specialists or physician in Pharmaceutical Medicine. Most medical specialties require a full time continuing education of a physician for five years, while a 'Master of Science' in most cases does not exceed a ▶ page 3

Questions & Answers

◀ two-year education and – as you say – it does not involve only physicians.

IFAPP WORLD: What actions do the DGPharMed and you as its President take to fully establish Pharmaceutical Medicine as a medical specialty?

Dr. Clemens: We will continue with our cooperation with the German 'Association of Clinical Pharmacology' (VKliPha) and its four scientific medical member societies and also continue the appropriate discussion with the German Medical Council. However, the Medical Council's regulations for continuing medical education and its definitions of medical specialties will automatically be revised from time to time in relatively long intervals; the last revision was completed in 2003. You see the point? The official recognition of Pharmaceutical Medicine as a medical specialty does not solely depend on the President's efforts of a single association.

IFAPP WORLD: Members of the DGPharMed are not exclusively physicians but include other specialists too. Without these specialists, the shortfall of professionals in Pharmaceutical Medicine would be even more striking – however, they never can qualify as a medical specialist in Pharmaceutical Medicine. Is then the 'Master of Science in Pharmaceutical Medicine' an adequate degree?

Dr. Clemens: The 'Master of Science in Pharmaceutical Medicine' is an adequate qualification, certainly. But then we offer all members of the DGPharMed, and non-members, an obviously less costly qualifying continuing education, which is certificated and up to the highest standards.

IFAPP WORLD: From a global perspective – new drug applications today are researched and developed in international or even global cooperation. To better facilitate this, international initiatives, with the IFAPP ahead, strive for the harmonization of qualifications in Pharmaceutical Medicine and its mutual recognition worldwide. What importance do you and the DGPharMed ascribe to these activities?

Dr. Clemens: It is particularly important. Since the DGPharMed is one of IFAPP's largest member associations it feels in duty bound and is committed to these goals and compelled to play a part in these activities.

IFAPP WORLD: IFAPP's 30 national member associations are all committed to further developing and strengthening Pharmaceutical Medicine in its respective countries. Would this boost competition – for instance when these countries compete to be awarded a contract for participation in a clinical research program of an industry sponsor? Or rather would it facilitate the international exchange of experience and know-how in terms of a fruitful cooperation in the patients favor with the hope of ever new pharmaceuticals?

Dr. Clemens: I do not feel any competition here. The exchange at international levels is crucial since all persons and parties concerned in Pharmaceutical Medicine are struggling with similar problems.

IFAPP WORLD: Will the 'internationalization' of Pharmaceutical Medicine be capable of bolstering its importance and reputation as well as leverage its recognition as a medical specialty? In short: Does the DGPharMed need the IFAPP?

Dr. Clemens: The requirements for the recognition of Pharmaceutical Medicine as a medical specialty in Europe have increased due to the expansion of the European Union. Before this expansion, a national recognition in two European member states automatically would have been initiated a European recognition process binding upon all member states. According to my knowledge now it would need appropriate recognitions in 11 member states to spur a European wide recognition. In this respect, the DGPharMed does not depend on IFAPP, however, the cooperation in this umbrella organization can help absolutely.

IFAPP WORLD: What do you and the DGPharMed expect from IFAPP to bolster Pharmaceutical Medicine within Germany and vice versa? What is the DGPharMed doing to sustain IFAPP in the same issues at an international level?

Dr. Clemens: I view this as a reciprocal give and take. GCP, GMP and GLP are international standards with national interpretations. For instance, cooperation within the IFAPP may facilitate the national activities and actions in this process of interpretation.

IFAPP WORLD: What are your objectives as DGPharMed President to boost prestige and importance of Pharmaceutical Medicine, to come closer to its recognition as a medical specialty and – last but not least – to strengthen and promote clinical research in Germany?

Dr. Clemens: We want to further increase our importance on the political level, although we already have a relevant voice, which is considered and respected by the ministry of health. Also we will extend our cooperation with our partners, in particular with the 'Association of the Scientific Medical Societies in Germany' (AWMF) and the German 'Association of Clinical Pharmacology' (VKliPha). Finally we want to further encourage the exchange of ideas with decision makers. Overall we will take clear positions regarding business location policies and we will submit constructive proposals on that.

IFAPP WORLD: Thank you for our conversation. ■

IFAPP's Calendar

◀◀ At ICPM 2008 all the hot topics within Pharmaceutical Medicine will be up for discussion. From state-of-the-art translational medicine to off-label pharmacotherapy, state-of-the-art trial design technology to niche indications in research, all interest areas will be covered. A very special session will be held on pharmaceutical crisis management focusing on underlying cause of phase III trial failure, which indeed is a horror scenario for all of us.

And what about medical research after marketing authorization with observational studies? There will be a separate session for all professionals in clinical trial operations providing the latest information about outsourcing strategies, patient recruitment practices and efforts to meet the increased quality demands while restraining cost-drivers.

Is the Far East of the globe the new trial paradise? This conference will review choices and chances of industrial research and development worldwide.

The pivotal role of the Pharmaceutical Physician will also be highlighted in the session 'From Science to Conscience' – what are the real choices made by the Pharmaceutical Physician. Additionally, there will be two key-note sessions: a debate between editors of scientific medical and pharmaceutical journals about bias in science, while Chief Medical Officers of top pharmaceutical companies will answer fundamental questions raised by the World Health Organization and other authorities regarding the entire pharmaceutical scientific world.

Update your knowledge in Pharmaceutical Medicine. Meet international colleagues to exchange ideas. Find answers to difficult daily life questions by talking with role-model colleagues. Contact pharmaceutical companies. And last but not least, be impressed by other cultures and delight in nice social events. Join us at ICPM 2008 in Amsterdam! For further information visit www.icpm2008.org.

Dr Rudolf van Olden, Chairperson, ICPM 2008 Organizing Committee ■

Amsterdam: Harbour and Central Station

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IFAPP News: Constitution

Weighted Voting Rights for IFAPP's Member Associations

In summer 2006 the DGPharMed, the 'German Society of Pharmaceutical Medicine' and second largest IFAPP member association, made the motion to assign the number of votes in non-constitutional matters depending on the size of a member association.

The proposed change to Article 10 Clause 3 of IFAPP's Constitution that at that time was in preparation for registration of IFAPP as a non-profit organization in the Netherlands read as follows:

"All Delegates of National Member Associations whose membership has not been discontinued have the right to vote. Each Delegate or Deputy-Delegate has one vote on matters relating to the Constitution. On non-constitutional matters the number of the votes held by the Delegates (or in their absence of their Deputy-Delegates) depends on the number of individual members of the respective National Member Associations. National Member Associations with 50 or fewer members have one vote; those with 51-100 members have two votes; those with 101-1000 members have three votes; those with 1001 or more members have four votes. Membership numbers will be taken as those at the time of the last paid annual fee."

The motion to forward this to the member associations for voting at the House of Delegates meeting in Seoul, September 2006, was carried unanimously.

At the 3 September 2006 House of Delegates meeting in Seoul, Korea, votes in favor of the amended IFAPP Constitution were available in writing from the member associations in Australia, Greece, Ireland, Serbia, South Africa, and Spain. Countries in attendance voting in favor of the new constitution were: Argentina, Austria, Belgium, Brazil, Italy, Japan, Korea, the Netherlands, Pakistan, Singapore, Sweden, Switzerland, UK, and USA. No votes opposing the amendment were received. In conclusion, a total of 20 votes (6 in absentia, 14 in attendance) in favor of the new Constitution carried the DGPharMed motion. ■

IFAPP's Regional Update

Pharmaceutical Medicine in Australia

The 'Australian Pharmaceutical Physicians Association' (APPA) is pleased to report the start of a new two-year Postgraduate Diploma course in Pharmaceutical Medicine under the auspices of Professors Ric Day and Ken Williams at the University of New South Wales (UNSW). The first few students came to the end of the initial academic year in 2006, and when the final module will be revised and completed in 2007, APPA will seek to have the course formally accredited. This already has been discussed with the IFAPP 'Council for Education in Pharmaceutical Medicine' (CEPM) and is a considerable achievement for the team here. The various UNSW drug development courses already attract some participation from the Asian region and there is an ambition to open up a UNSW campus soon in Singapore, which in time might extend delivery of the course.

Another activity APPA tried to promote in 2006 was a better awareness of the role of pharmaceutical physicians and the specialty of Pharmaceutical Medicine as a career option to medical students and young medical graduates. In March 2006, APPA had a stand at a medical careers convention and attracted some interest from the target audience, most of whom did not have a clue what was meant by the term Pharmaceutical Medicine. There were some contacts with the medical students association and APPA may be able to present at the next annual conference of the medical students association. In addition, APPA sent them a brief pamphlet on Pharmaceutical Medicine, which was used as part of the giveaways at the careers convention. "We would like to explore further the opportunity to increase awareness of our specialty in medical schools," said an APPA representative.

With greetings from Down Under by Dr Rob Creek, APPA's Past President, Sidney, Australia ■

Dr Rob Haski manning APPA's stand at a medical careers convention in March 2006.

IFAPP's Regional Update

Argentina: Clinical Research Training Course

Following the success of previous courses, the 'Argentinean Pharmaceutical Medicine Society' (La Sociedad Argentina de Medicina Farmacéutica – SAMEFA) launches its 'Fourth Training Course for Clinical Research Associates (CRAs) and Study Coordinators'. This course spans 65 hours of active training, beginning in early April 2007 and ending in late November 2007. Participants will be trained in the essential topics of:

- functional role of the clinical test/study monitor and coordinator and its importance
- development plan of a pharmaceutical product and protocol design
- national and international regulatory issues
- monitoring of a clinical study according to Good Clinical Practice (GCP)
- importance of quality and protection of data
- ethical issues in clinical investigations

The course is open to students, physicians and other medical science graduates (biologists, biochemists, nurses, pharmacists), whether working or not in clinical-pharmacological investigation areas.

Clinical research in Argentina is growing quickly and requires increasing numbers of trained staff. SAMEFA, the distinguished association with the vast majority of experts qualified in clinical research in its membership, has established training courses to share their knowledge and experience with others, quickly meeting the ever-growing demands.

Dr Luis Collia, IFAPP President and IFAPP Delegate from Argentina ■

IFAPP's Vision Statement

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 Members: Elections

Argentina: New Board of SAMEFA

The new board of the 'Argentinean Pharmaceutical Medicine Society' (La Sociedad Argentina de Medicina Farmacéutica – SAMEFA) was elected at the General Assembly for the period 2007-2008. President of SAMEFA is Dr Daniel Mazzolenis; Dr Luis Collia was affirmed as IFAPP Delegate.

In order to encourage scientific and teaching activities, SAMEFA maintains the Scientific Committee, which supports strong relationships and cooperation with IFAPP, regulatory authorities, other scientific societies and the Faculty of Pharmaceutical Medicine. ■

New IFAPP Delegate from Turkey

The 'Turkish Association of Medical Profession Members in the Pharmaceutical Industry' (ISMED) held its General Assembly in December 2006 electing the new President and the new IFAPP Delegate.

The new President of the Turkish ISMED is Dr Ilker Gelisen. Dr Bengi Koyuncu was appointed the new IFAPP Delegate from Turkey succeeding Dr Yesin Üresin who was instrumental in ISMED's contributions to IFAPP matters in the first two years of IFAPP membership.

Prof Dr Sule Oktay will continue as a member of the IFAPP 'Council for Education in Pharmaceutical Medicine' (CEPM). ■

Stay Tuned

Navigating the Regulatory Maze

Representatives from micro-, small- or medium-sized enterprises (SMEs) and their stakeholders participated in the first workshop for SMEs held in London, UK, in February 2007 by the 'European Medicines Agency' (EMEA). The objective of the workshop was to provide practical advice and tips for SMEs on procedures for orphan designation, scientific advice, and the centralized application for marketing authorization. Presentations were also made on inspection compliance issues, electronic submissions and pharmacovigilance. Representatives of the pharmaceutical industry moderated the discussion following each of the four sessions. A copy of all workshop presentations is available in the worldwide web: www.emea.europa.eu/SME/SMEworkshops.htm

European Parliament + Council

New Legislation on Pediatric Medicines

A new European regulation on pediatric medicines was implemented in January 2007. According to the 'European Medicines Agency' (EMEA) the Pediatric Regulation aims to improve the health of Europe's children by:

- stimulating research and development of medicines for use in children
- ensuring that medicines used to treat children are appropriately tested and authorized
- improving the availability of information on the use of medicines for children

These will be achieved through a system of requirements and incentives. For further information, please refer to the article "Better Medicines for Children" below.

A new scientific expert Pediatric Committee within EMEA is responsible for assessment and agreement of pediatric investigation plans, which set out measures for studying the medicinal product concerned in the pediatric population. It also has to decide on waivers and deferrals, granted in certain circumstances where pediatric studies are not required or desirable, and where the initiation or completion of pediatric studies should be deferred until appropriate adults studies have been performed.

The Pediatric Committee will also work with the European Union's member states – building on work already performed by EMEA's Pediatric Working Party (PEG) – to establish an inventory of the therapeutic needs for children. It will also be advising the EMEA on the development of a European network for clinical trials in children, based on existing networks.

As part of an internal action plan for implementing the Pediatric Regulation, EMEA and European Commission published a joint document on their implementation priorities. The Agency also has published a FAQ (frequently asked questions) document intended to help companies with the new legislation. ■

Details provided by the EMEA are available online at www.emea.eu.int/htms/human/peg/pegfaq.htm or at http://ec.europa.eu/enterprise/pharmaceuticals/paediatrics/index.htm by the European Commission.

The 'European Pediatric Regulation' (EC No 1901/2006)

Better Medicines for Children

Here are summaries and brief comments from the main lectures of the 'First Annual Scientific Conference & Provider Exhibition', hosted by the 'Belgian Association of Pharmaceutical Physicians' (BeAPP) on 15 March 2007 in Brussels, Belgium. The scientific program focused on pediatric pharmaceutical research with a keynote session and three parallel sessions on risk management, access to market and advances in Pharmaceutical Medicine.

Keynote Session

A New Era for Pediatric Pharmaceutical Medicine

Chair: Daniel Brasseur, Chair of CHMP at the 'European Medicines Agency' (EMEA) (United Kingdom). Speakers: Brasseur: The European Pediatric Regulation; Peter Verdru (USA and Belgium): The industry experience with the US pediatric exclusivity rules; Jose Ramet (Belgium): Practical experience in clinical trials with children; Victoria Kitcatt (United Kingdom): Legal aspects on the European Pediatric Regulation; Greet Musch (Belgium): The European Pediatric Regulation and the impact on national health authorities.

'European Pediatric Regulation' Now Effective

Following the publication of the 'European Pediatric Regulation' (December 2006) the legal provisions are now effective (January 2007) taking staggered steps in their implementation by the national authorities of the European Union's member states. As Daniel Brasseur explained, the main task of EMEA's Pediatric Committee with a representative of each member state consists of assessing Pediatric Investigation Plans (PIP) that pharmaceutical companies are requested to submit early in the development phase of new drugs. The PIP should contain all elements – formulations, pre-clinical data, clinical trial ▶ page 6

European Pediatric Regulation

◀ designs, etc. – needed to undertake studies in children of all age classes; a time-table should be agreed. Waivers for unnecessary studies (no pediatric indication, e.g., Alzheimer's and Parkinson's disease) will be carefully considered by the Pediatric Committee.

The Idea Behind It

The idea is to run adult and pediatric clinical trial programs in parallel in order to have access to new medicines both in the adult and pediatric populations. The reward for companies successfully finishing a PIP is a 6-month extension of the drug's patent life. Provisions are also provided for 'older' off-patent drugs. A successful PIP will provide the company with a pediatric use Marketing Authorization (MA) for the medicine concerned, indicating it is suitable for a specific age group.

The 'European Pediatric Regulation' foresees additional tasks supervised by the EMEA: an inventory of pediatric needs, collection of data on pediatric off-label use, and creating a network of pediatric investigators.

EMEA's Pediatric Committee will have to evaluate more than 200 PIPs in 2007 providing an assessment, which is based on EMEA's summary report. The challenge will be to collaborate closely within the EMEA and the national authorities.

As explained by Ms. Greet Musch from Belgium's 'Federal Agency of Medicines', the impact of the Pediatric Regulation on the member states is not well known: actually the Belgian Federal Agency is setting up a network of pediatric experts and investigators.

Experience of the Industry with the US Pediatric Exclusivity Rules

The US 'Food and Drug Administration' (FDA) issues Written Requests (WR) to holders of approved applications for pediatric studies when it determines that data on the drug use in the pediatric population may provide health benefits. As an incentive to industry, a 6-month period of pediatric marketing exclusivity is provided. This act stimulated the industry to increase the number of well-controlled clinical trials in children. It is a moral imperative to formally study drugs in children; previously "pediatric patients and not clinical trial subjects were being misused as guinea pigs." Of course what is needed is synchronization and a mutual recognition of the PIPs between FDA and EMEA.

Session 2
Access to Market

Chair: Philippe Van Wilder (Belgium). Speakers: Graham Lewis (United Kingdom): Market trends in the pharmaceutical world; Dominique Dubois (Belgium): The role of patient reported outcomes in market access; Bruno Van Eesbeeck (Belgium): Reimbursement in hospital environment: The new setting.

Market Trends in the Pharmaceutical World

As Graham Lewis predicted, global pharmaceutical market growth and size through the year 2010 shows geographical shifts and a slow-down in the market: he predicted global growth of 6% and European growth of 5% with a declining share of the top 5 European countries and Japan, while the US is recovering due to Medicare.

Reimbursement policies further favor generics, while research and development (R&D) productivity will face challenging times with fewer launches of new molecular entities (NMEs); in 2006 only 28 NMEs were approved. Overall, brand growth will decline due to a loss of brand protection, generic penetration and erosion. Innovations now focus mainly on life-threatening diseases such as cancer or debilitating diseases (e.g., Alzheimer's disease, rheumatoid arthritis, chronic obstructive pulmonary disease – COPD).

More often innovative drugs will be derived from biotechnology, which will induce very high treatment cost. This will add to the financial problems of health care with the consequences of tightening cost-containments and boost the demand for evidence-based value. Health technology assessment is here to stay.

A reassessment of health policy to allow access to innovative drugs is a major priority for the European Union.

Dr Henri Pintens,
IFAPP Deputy-Delegate, Belgium ■

IFAPP's Calendar

Patient-tailored Pharmacotherapy

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

As clinical pharmacology is one of the cornerstones in the Pharmaceutical Medicine profession, please note in your calendar that the 8th conference of the 'European Association for Clinical Pharmacology and Therapeutics' (EACPT) with the conference theme of 'patient-tailored pharmacotherapy' will be held from 29 August to 1 September 2007 in Amsterdam, the Netherlands.

EACPT provides professional and educational information on clinical pharmacology and pharmacotherapy. In collaboration with the IFAPP, EACPT has organized a very special and interesting afternoon session focusing on Clinical Research in Europe after the EU Directive for Thursday, 30 August 2007. Key-note speakers on ethics reviews, clinical operations, audits and modern trial design and regulations have been confirmed. The future of investigator-initiated trials (IITs) and the experience with competent authorities and ethics committees also will be discussed.

In addition, a special IFAPP satellite session is planned addressing the key role of Pharmaceutical Medicine. 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)? Invest in your professional education and join the EACPT 2007 in Amsterdam. Full information regarding the program, the speakers and the location is available at www.eacpt2007.nl.

Dr Rudolf van Olden, Member of the Organizing Scientific Committee ■

Tulip fields in bloom – spring in the Netherlands

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Stay Tuned

Japan & the European Union

Confidentiality arrangements agreed

Confidentiality arrangements were agreed recently between the 'European Commission' (EC) and the 'European Medicines Agency' (EMEA) on the one side and the Japanese 'Ministry of Health, Labor and Welfare' (MHLW) and Japanese 'Pharmaceuticals and Medical Devices Agency' (PMDA) on the other at a bilateral meeting in Tokyo.

The new arrangements, which are built on previous cooperation, will allow exchange of confidential information between the parties as part of their regulatory and scientific processes, both before and after a medicine has been approved. According to an EC-EMEA press release the confidentiality arrangements cover human medicines subject to evaluation or authorized under the centralized authorization procedure as well as medicinal products authorized at national level by the European Union's member states that are subject to official EU arbitration and referrals. ■

R & D for New Medicines

Biomarkers gaining importance

The 'European Medicines Agency' (EMEA) in collaboration with the 'European Federation of Pharmaceutical Industries and Associations' (EFPIA) organized a first joint biomarkers workshop in December 2006. All the presentations are available at the EMEA website at www.emea.europa.eu/htms/human/biomarkers/biomarkers.htm in the worldwide web.

At this site the EMEA also provides a short report regarding the main topics, which attests: "Overall the prospects for the biomarkers are very positive, although generally the development is still at a very early stage. Moreover, participants were of the view that one bottleneck to development is the pre-analytical phase and that prospective sampling of fresh frozen material required for most techniques should be promoted with focus put on methods that improve reproducibility. Another issue, in particular from the statistical point of view, was the importance of sharing data among companies as required for validation of surrogate endpoints. The role of biomarkers for safety was briefly mentioned and will require more discussions." ■

Beyond the Horizon

Abridged Report from ICPM 2006

– Seoul, Korea, 3-6 September 2006 –

Report on Session H

Drug Safety Management

Chair: Rebecca Wang (USA). Co-Chair: Byeong-Ju Park (Korea). Speakers: Kimihiro Kasamo (Japan): Pharmacovigilance during clinical development; Stewart Geary (Japan): Post-Authorization Safety; Kenneth Hartigan-Go (Philippines): Pharmacovigilance Planning in Risk Management: the key to ensuring proper use of medicines

The importance of drug safety management during development and marketing was emphasized in this session.

Dr Kimihiro Kasamo noted that CIOMS VI ('Council for International Organizations of Medical Sciences') recommended applying the term 'pharmacovigilance' to activities related to the detection and management of adverse drug reactions during pre-marketing clinical development in addition to its use in the post-marketing setting. In this sense, the 'International Conference on Harmonization' (ICH) E2E Guideline on 'Pharmacovigilance Planning' also has applications to the period of clinical development for instance, by listing identified and potential unidentified risks before the 'first-in-man' trial with updates subsequently as knowledge about the compound grows.

Dr Stewart Geary presented on pharmacovigilance in the post-marketing setting, noting first that a standard model of pharmacovigilance has emerged with assessment of new adverse event information from spontaneous reporting and new clinical and non-clinical studies driving changes to a 'Core Company Data Sheet' (CCDS). This in turn drives company-initiated changes in approved labels around the world. To this standard model additional techniques have now been added to query large databases for new safety signal detection. However much work remains to be done in evaluating the strengths and weaknesses of these automated techniques based on detection of reporting 'disproportionalities' and it is hoped the new CIOMS VIII Working Group on Signal Detection will develop a consensus 'Points to Consider' on the subject. Another addition to the standard model is the growing use of formal 'Risk Management Plans' where the US 'Food and Drug Administration' (FDA) and European regulatory authorities guidance have taken a leading role in further developing the concepts of risk detection started in the ICH E2E guidance into methods for risk management and minimization.

Dr Stewart Geary, Japan, at his presentation on pharmacovigilance

Dr Kenneth Hartigan-Go made a call for taking a broad approach to risk management in Asia by appreciating the many different ways that patient safety can be threatened by improper pharmaceutical promotion, supply and management. He gave examples of how exaggerated or unfounded claims of efficacy can endanger patient safety, and noted several cases of illegal importation of unapproved 'natural remedies,' beauty products and anabolic steroids which contained either regulated, unapproved or banned ingredients which present risks to consumers. Substandard products where lack of proper quality controls resulted in inappropriately low levels of active ingredients, or confusing trade names, expiration dates (e.g., day-month-year vs. month-day-year) and abbreviations were also noted to create potential risks to patient health. Dr Hartigan-Go encouraged conference participants to take a broad, holistic approach to risk management in the best interests of patient safety.

Dr Stewart Geary, member of the IFAPP Executive Committee, Japan ■

Dates & Deadlines

11-13 April 2007 • Washington, DC, USA
QT Issues in Drug Development

This event on QT Issues in Drug Development – the evolving science, practical issues, and regulatory implications – is co-sponsored by the US 'Food and Drug Administration' (FDA) and the US 'Heart Rhythm Society'.

"This program will bring together a faculty of regulatory, industry, and scientific leaders in the field to explore and discuss the evolving science surrounding drug development and cardiac repolarization. The meeting will focus on the current state of the art, new directions that can meaningfully impact the development of pharmaceutical agents, and practical challenges and possible solutions."

www.fda.gov/cder/workshop.htm in the worldwide web.

20-24 April 2007 • Seattle, Washington, USA
31st Annual ACRP Global Conference and Exhibition

(ACRP – Association of Clinical Research Professionals) combined with the annual meeting of the 'Academy of Pharmaceutical Physicians and Investigators' (APPI)

"This year's program will offer more than 150 pre-conference workshops and concurrent education sessions. That's 20% increase in size over the 2006 program. The 2007 program will feature at least 10 panel discussions and nearly 40 interactive sessions. The APPI program returns for the second straight year as a major component of the conference."

www.acrp2007.org in the worldwide web.

15-17 May 2007 • Philadelphia, PA, USA
Biomarker World Congress 2007

"The Biomarker World Congress 2007 is dedicated to all areas of biomarker research spanning the pharmaceutical and diagnostic pipeline. The meeting … offers a balance of scientific sessions covering the latest research and strategic presentations and brainstorming sessions for the decision makers."

www.biomarkerworldcongress.com in the worldwide web.

23-24 May 2007 • London, UK
7th Annual e-Clinical Trials Conference

"The e-Clinical Trials 2007 conference will bring together the experiences of the major pharmaceutical companies to give practical and adaptable examples of incorporating electronic systems into clinical trials and is set to be one of the most comprehensive events this year."

www.clinicaltrialsevents.com in the worldwide web.

7 June 2007 • Brussels, Belgium
IFAPP's CEPM Meeting on Mutual Recognition of Diplomas in Pharmaceutical Medicine

The IFAPP 'Council for Education in Pharmaceutical Medicine' (CEPM) will hold a meeting with the Directors of Postgraduate Courses in Pharmaceutical Medicine (PM) from European Universities to deal with mutual recognition of PM-Diplomas. IMI is a proposed partnership between the 'European Commission' and the 'European Federation of Pharmaceutical Industry and Associations' (EFPIA).

The objectives of this meeting are to • foster communication and interaction between the various courses and the CEPM • work towards mutual recognition of Diplomas in Pharmaceutical Medicine • prepare the ground for the creation of a 'European Federation of Postgraduate Courses in Pharmaceutical Medicine' • agree on the participation in the IMI-SRA project ('Innovative Medicines Initiative' – IMI; 'Strategic Research Agenda' – SRA).

'IFAPP World' will provide a report from this important meeting in its issue 2/2007.

12-13 June 2007 • Philadelphia, PA, USA
6th Annual World Pharmaceutical Congress

www.worldpharmacongress.com in the worldwide web.

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

Please note the article *"Patient-tailored Pharmacotherapy"* on page 6.

www.eacpt2007.nl in the worldwide web.

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

Full two-day congress to discuss issues surrounding • ICH and FDA updates • programs of Latin American regulatory guidelines and ethical issues • infrastructure and components of clinical research • perspectives on the development of clinical research in Latin America.

Organized by the 'Drug Information Association' (DIA) and the 'Sociedade Brasileira de Medicina Farmacêutica' (SBMF) in collaboration with the IFAPP and the 'Argentinean Pharmaceutical Medicine Society' (La Sociedad Argentina de Medicina Farmacéutica – SAMEFA).

13-14 November 2007 • Philadelphia, PA, USA
Pharmaceutical Strategy Series' 2nd annual executive forum Post-Approval Drug Safety Strategies: Approaches and Processes to Reduce Risk

"Improving products' effective clinical safety will increase the industry's fundamental value proposition to patients, healthcare providers, payors and regulators. The program will focus on pharmacovigilance program implementation and specific strategies and approaches to creating true value from a post-approval drug safety program. The special two-day executive forum will tackle many of the pressing issues that executives are facing today."

www.healthtech.com/2007/PHV/index.ASP in the worldwide web.

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 1.

www.icpm2008.org in the worldwide web.

THE FLAG

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