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CONTENT	
Personal Snapshot Professor Peter Stonier received the APPI Lifetime Achievement Award	3
IFAPP Updates Election of the IFAPP Executive Commit	3 tee
IFAPP Updates Singapore: the 30th Member Associatio	3
IFAPP Members – Elections New Presidents of IFAPP Members Australia and Germany	4
IFAPP's Vision Statement	4
Frequently Asked Questions TRIPS & pharmaceutical patents: fact sheet What is compulsory licensing?	4
Beyond the Horizon 6 Abridged Reports from ICPM 2006 in Seoul, Korea	-10
IFAPP News Poll amongst IFAPP's national Member Associations: High Importance of IFAPP Code of Ethical Conduct	11 2's
The next IFAPP World issues	12

President's Letter

Dear Colleagues

During the time spent in Seoul at the 'International Conference on Pharmaceutical Medicine' (ICPM) 2006, I felt as if it all seems to have been a whirlwind of faces and places. Now that the Conference is finished, I've been able to step back and more fully appreciate the truly unique experience of this ICPM: the beautiful setting, the excellence of the program and the speakers, the chance to reconnect with friends and acquaintances and the opportunities to establish connections with new ones, and of course, the charming culture and the hospitality of the Korean people.

With more than 500 attendees representing 31 countries, this year's ICPM has featured a number of special sessions, it has generated new ideas, and we have intensively communicated in an open way in an atmosphere of trust in order to establish a yet better and stronger relationship between all of us. Although we represent different cultures and speak different languages we share similar ideals and objectives – that became clear more than ever during our communications in Seoul. In Seoul, the IFAPP's Executive Committee members worked intensively on education programs, page 2

Questions & Answers



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

From Scenario to Reality

The Ever Changing World of Medicine

In the opinion of several scientists and market researchers, the World of Medicine currently is in transition, struggling to cope with many conflicting demands and developments. While the overall cost for research, development and clinical evaluation of new molecular entities continues to increase, there is a decrease in the output of new innovative drugs and the income they generate. Additionally, many experts predict an individualization of medicine - believed to contribute more and more to the general progress in medicine and driven by genomics, proteomics, bionics, and their appropriate technologies, rather than by pharmacy or chemistry. However, this progress might further increase overall medical care cost, while at the same time public health budgets in many countries face ever more constraints.

Dr Luis Francisco Collia, the new president of the International Federation of Associations of Pharmaceutical Physicians (IFAPP) said in an interview with Eckhard Boettcher-Buehler from 'IFAPP World': "This does really challenge Pharmaceutical Medicine in general and the IFAPP in particular." For details read the full interview.

IFAPP's Calendar



'ICPM 2008' in Amsterdam

Developing Pharmaceutical Care: Medicines after the Blockbuster Era

The 15th 'International Conference on Pharmaceutical Medicine' – ICPM 2008 – is to be held 7-10 September 2008 at the Okura Hotel Amsterdam in the Netherlands.

The theme of ICPM 2008 – supported by the Netherlands' authority – is 'Developing Pharmaceutical Care: Medicines after the Blockbuster Era.' For ongoing information the official ICPM 2008 website has already been set up at www.icpm2008.org where you can order an ICPM 2008 newsletter to keep up to date.

On behalf of the 'Netherlands Association of Pharmaceutical Physicians' (NAPP; www.nvfg.nl) and the 'International Federation of Associations of Pharmaceutical Physicians' (IFAPP; www.ifapp.org) the Chairperson of the Organizing Committee, Dr Rudolf van Olden, would like to welcome you to the ICPM 2008 in Amsterdam!



Questions & Answers

From Scenario to Reality

■ IFAPP WORLD: Dr Collia, is the lead text description of the ever-changing World of Medicine a scenario of people influenced by science fiction or is it already a reality?



Dr Collia: From my point of view, this is a reality that has emerged recently and, of course, will gain ground more and more in the next couple of years. Indeed, the World of Medicine is in a transition with far-reaching and grave consequences.

IFAPP WORLD: Then do you face any changes in the conception of Pharmaceutical Medicine and do you expect Pharmaceutical Medicine and the new biotechnologies genomics, proteomics and bionics to complement one another rather than compete?

Dr Collia: Until now Pharmaceutical Medicine has been just watchfully noticing all these changes that you describe, while many pharmaceutical companies already have settled contracts and formed co-operations with biotech companies. And such new products have already entered the market.

However, biotechnologies – genomics, proteomics and bionics – afford new ways in

research and development for new treatments with novel mechanisms of actions. That's why Pharmaceutical Medicine has to care about ethical considerations and adjust the guidelines for clinical trials, Good Clinical Practice (GCP), and other issues regarding biotechnological investigations in humans.

However, in my belief all these progresses and changes finally will provide a great benefit for Pharmaceutical Medicine overall.

IFAPP WORLD: What will be the main challenges in the next two years for Pharmaceutical Medicine in general and for the IFAPP in particular?

Dr Collia: Just very briefly and there might be particular issues and aspects not fairly considered right away – in my opinion, the main challenges for Pharmaceutical Medicine will be the regulatory issues. Without a doubt, there is a demand for guidance and guidelines when genomics, proteomics, bionics and their technologies or products were first applied to humans. We also need to use common sense regarding ethical aspects for instance in stem cell research and cell therapy. And last but not least, we should establish rules in order to globalize clinical trials for simplifying the development of new drugs. And of course all this

needs to be escorted by an increased, harmonized and as necessary adapted education of pharmaceutical physicians and clinical research professionals in Pharmaceutical Medicine.

In this ever changing environment the IFAPP needs to be recognized and accepted as an authoritative voice on medical and pharmaceutical aspects of drug research and development as well as on the specialty of Pharmaceutical Medicine by governmental, regulatory and academic bodies, by the pharmaceutical industry as a whole, by all healthcare professionals including healthcare providers, by the media and the public.

In order to achieve all this we have to work hard to develop and foster programs for Continuing Medical Education (CME) and Continuing Professional Development (CPD) in Pharmaceutical Medicine in IFAPP's national Member Associations. The aim is the global harmonization of courses and diplomas in order to develop the knowledge and skills of professionals in Pharmaceutical Medicine to the maximum. These points are the basis for the international recognition of Pharmaceutical Medicine as a specialty.

We also have to work hard in configuring an effective and reliable infrastructure of our federation to get the international dissemination of the highest standards of Pharmaceutical Medicine practices.

IFAPP WORLD: As the new IFAPP president, how will you deal with all this?

Dr Collia: As IFAPP's president I will maintain and promote all the activities that allowed us to grow as a global federation in recent years. In order to increase IFAPP's impact and authority I will try to attract new national associations for IFAPP membership. China, India, Canada and some Latin American countries are very important in this regard. And of course I will work hard to increase IFAPP's visibility and high profile in order to reach our 5-year plan objectives.

But we all need to further communicate all IFAPP issues outlined in IFAPP's statements on its mission, aims and objectives and suit action to our words. This action needs to cover not only global issues but also international, regional, and national issues with the presence and active participation of IFAPP's Executive Committee members when ever and where ever appropriate in local activities in distant countries.

Firmly, I believe that if we can get all these objectives, IFAPP will be recognized as a high profile and authoritative voice in the World of Medicine.

IFAPP WORLD: Thank you.

President's Letter

Dear Colleagues

drug development issues, clinical trials aspects, regulatory affairs, ethical considerations as well as opportunities and challenges in pharmaceutical medicine overall. All that we have discussed and concluded we now will communicate to our national Member Associations.

Our main goals and issues during the next two years along the way to the next ICPM in 2008 in Amsterdam, the Netherlands, will be the following: to improve and intensify the relationship between IFAPP's national Member Associations; and to develop more regional events with active participation in the annual meetings and congresses of international bodies like the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMEA), and others, in order to increase the



See you in Amsterdam!

perception of IFAPP as what it is – an international forum for all the organizations of Pharmaceutical Physicians world-wide, dealing with matters brought to its attention by its national Member Associations.

The success of this year's ICPM could not have happened without all the efforts of a lot of dedicated volunteers under the leadership of Dr Yil-Seob Lee. I also would like to recognize the work of the Secretary General, the Treasurer, the Scientific and Logistics Committee, altogether to accomplish this wonderful and highly scientific ICPM. We are all well aware that they have worked very hard in order to get these excellent results and to incite more than 500 experts to come to Seoul and participate at the ICPM, which is excellent and very important.

On behalf of IFAPP, I thank our Korean colleagues for this excellent ICPM.

I'm looking forward to meeting all of you again at the next ICPM in Amsterdam, the Netherlands, in 2008. Please don't forget to diarize the 7th to 10th of September in 2008 – please put an ICPM-mark in your calendars now!

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



IFAPP Update: Boards

Election of the IFAPP Executive Committee

During the House of Delegates Meeting on September 3rd, 2006 in Seoul the proposed Executive Committee of the 'International Federation of Associations of Pharmaceutical Physicians' (IFAPP) for the 2006 to 2008 period was approved by unanimous vote of House of Delegate members in attendance as follows:

President: Luis Collia (Argentina); Past President: Chris Allen (USA); President Elect: Gerfried Nell (Austria); Secretary: Stewart Geary (Japan); Treasurer: Herman Lahon (Belgium)

Membership as at December 1st, 2006: Mirela Barbu (Switzerland), Jane Barrett (UK), Sander Becker (co-opted member, Australia), Kurt Bestehorn (Germany), Domenico Criscuolo (Italy), Jean-Paul Deslypere (Singapore), Gustavo Kesselring (Brazil), Churl J. Kim (Korea), John Lee (Sweden), Antonio Luque-Serrano (Spain), Anne-Marie Masquelier (France), Dimitris Michailidis (Greece), Rudolf van Olden (the Netherlands), Johanna Schenk (co-opted member, Germany), Yesin Üresin (Turkey), Victoria Vazquez (Mexico).

Secretariat: Caroline van Bruggen (the Netherlands) IFAPP ■

IFAPP Update: Members

Singapore: the 30th Member Association

The IFAPP is proud to announce and welcome its 30th member: the 'Singapore Pharmaceutical Physicians Association'. During the House of Delegates Meeting on September 3rd, 2006 in Seoul the new 'Singapore Pharmaceutical Physicians Association' (SIPPA) was approved as 30th IFAPP member. The aims of the organization are to achieve recognition of Pharmaceutical Medicine as a specialty in Singapore, education in Pharmaceutical Medicine, and regional expansion of clinical trials and clinical research. The organization's bylaws are patterned after those of IFAPP.

SIPPA's delegate to IFAPP is Professor Dr Jean-Paul Deslypere, SGS Life Sciences. According to Professor Dr Deslypere, SIPPA's first meeting was attended by 17 people, all physicians and experts in Pharmaceutical Medicine. Since the first meeting the SIPPA membership has increased to 31.

All members of the IFAPP House of Delegates wish SIPPA a lot of success and trust in a fruitful co-operation. IFAPP ■

Personal Snapshot



Professor Peter Stonier received the APPI Lifetime Achievement Award

Professor Peter Stonier:

"Pharmaceutical physicians and Pharmaceutical Medicine represent the medical scientific discipline concerned with discovery, development, evaluation, registration, monitoring and medical aspects of marketing of medicines for the benefit of patients and public health."

Professor Peter Stonier's career totally embraces the development of Pharmaceutical Medicine, professional representation of pharmaceutical physicians and many aspects of education and training in the discipline. He has contributed extensively to the recognition of Pharmaceutical Medicine as a medical specialty in the United Kingdom, in particular in developing 'Higher Medical Training Guidelines' in Pharmaceutical Medicine in the run-up to and following parliamentary approval and listing of the specialty in April 2002. His work has also included an active role in the introduction of Continuing Medical Education (CME) and Continuing Professional Development (CPD) for pharmaceutical and regulatory physicians.

Indeed, Peter Stonier's efforts and achievements were instrumental in paving the way for Pharmaceutical Medicine's international recognition as a distinct medical discipline with high expertise in clinical research, drug development and life-cycle management of medicines within healthcare overall. Today Peter Stonier remains a key figure in enhancing the profile of the discipline.

Recently the 'Academy of Pharmaceutical Physicians and Investigators' (APPI), based in the USA, recognized Peter Stonier's distinguished contribution and leadership with its esteemed Lifetime Achievement Award.

In brief:

Peter Stonier was born right after World War 2, and after academic and research degrees, medical qualification and clinical experience he joined the pharmaceutical industry and has worked as a pharmaceutical physician in the Hoechst group of companies in the UK from 1977, latterly as Medical Director and Board Director until 2000. Hoechst became Hoechst Roussel, then Hoechst Marion Roussel and finally Aventis, providing Peter Stonier with first hand experience in management of change. He has now left big pharma, but is actively involved in the industry as medical director of Amdipharm, a new UK pharma company.

Peter Stonier also has led in multiple aspects of Pharmaceutical Medicine with many associations. He was President of the 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians' of the UK 1997 to 2001, having been associated with the Faculty since its formation from 1986 and inauguration in 1989. He was President of IFAPP 1996 to 1998 and prior to that Chairman of the 'British Association of Pharmaceutical Physicians' (BrAPP).

All of these positions were at a time ripe for the introduction of education and training in Pharmaceutical Medicine at both local UK and international levels, for the endeavor to harmonize international activities in this, and for the development and maintenance of standards in the principles and practices of ethical pharmaceutical medicine.

Academically, Peter Stonier was the first visiting professor in Pharmaceutical Medicine at the University of Surrey, establishing with industry and academic colleagues in 1993 the first Master of Science program in Pharmaceutical Medicine. He also was a founding father of the 'International Journal of Pharmaceutical Medicine' and has had extensive authoring and journal editing experience. He has served as President of the 'Royal Society of Medicine's Section for Pharmaceutical Medicine and Research'. In 2002 he was made the first Honorary Member of the Belgian College of Pharmaceutical Medicine in recognition of his contribution.

His character:

Those outside Peter Stonier's circle of family and close friends might wonder how this most straightforward of men manages to sustain such a broad portfolio of commitments. "Delegation. You have to get rid of things very quickly!", he once answered when questioned by a 'Good Clinical Practice Journal' editor. However, this belies his own understanding and active involvement in issues; through attention to detail he is well grounded and also has time to be attentive to other people's thoughts, challenges and problems, as well as delights – yet remains



Personal Snapshot

■ straightforward in all his obligations, responsibilities and decisions, reflecting a well organized and disciplined mind. He is noted for his 'stickability', problem-solving and steadfast pursuit of issues until a satisfactory outcome is reached, no matter how long it takes. All good traits for this April-born Taurean!

In a perfect illustration of this successful life of multi-tasking, some years ago a journalist noted that after their interview Peter Stonier's next appointment was to pick up his son and daughter from nearby schools: "A father's routine of looking after his children, seemed to fit importantly though quite tightly into the Professor's weekly schedule." Equally his wife, Beth, the director of her own Contract Research Organization (CRO), shares their numerous life demands. To achieve this balancing act of family and professional demands, sometimes something has to give and Peter had to cease working towards an Open University honors degree in General Arts when his son was two years old; "It wasn't really working out when, after a sleepless night and a hard day in the office, I had to go to a lecture on Post-Modernism!"

Today, outside work, Peter Stonier is a bon vivant, is devoted to opera and keeps fit walking the family's cocker spaniel, practicing lacrosse with his daughter, 13, or, less often, rugby with his son, now a 16 year old teenager. He also moors a motor boat in the south of France and always enjoys cruising in search of a good restaurant.

Peter Stonier is an authority in Pharmaceutical Medicine, a connoisseur of the phar-

maceutical industry and an advocate for pharmaceutical physicians. He is full of vitality, while his common sense, intellect, and British dry humor are impressive. Although he has maintained a truly constructive and optimistic approach to life, he also expresses some concern regarding the changes and challenges facing the medical industry: "Medically-trained staff working in industry are not the conductors of the orchestra any more. Medicine in industry has lost out to lawyers and financial analysts."

Nevertheless Peter Stonier's firm beliefs are rooted in the role of physicians in the development and life-cycle management of medicines, bringing professionalism and their relevant clinical and often scientific training and expertise to bear on problems and issues relating to drug development and maintenance which have an impact on the safety and well-being of patients. More than ever, pharmaceutical medicine as a distinct specialty at the interface of clinical medicine, the pharmaceutical industry and government, can be the focus of the work of industry physicians in upholding standards of their work, both ethical and scientific.

Conversely, their own future more than ever depends on embracing the specialty of pharmaceutical medicine, with its inherent ethical, professional and quality standards working in the interests of patient safety and welfare. This provides a clear identity for industry doctors with a corporate and public face as well as a voice that can impact change.

Dr Christopher Allen and Eckhard Boettcher-Buehler **IFAPP Members: Elections**

New Presidents of IFAPP Members Australia and Germany

The 'Deutsche Gesellschaft für Pharmazeutische Medizin e.V.' (DGPharMed; German Society of Pharmaceutical Medicine; www.dgpharmed.de) has held its general assembly on October 26th, 2006 in Würzburg, Germany.

In line with their constitution, i.e., subsequent to a 2-year president-elect period, the new DGPharMed president is Dr med Norbert Clemens, Analytica International GmbH, Loerrach, Germany.

The new IFAPP delegate from DGPharMed is the immediate past-president Dr med Kurt Bestehorn, MSD Sharp & Dohme GmbH, Haar, Germany. New president elect is Dr med Reinhard Hoenig, Moenchengladbach, Germany. Congratulations!

The new President of the 'Australian Pharmaceutical Physicians Association' (APPA; www.appa.net.au) for 2006 and 2007 is Dr Jeffrey Hassall. Dr Hassall is Medical Director Australia and New Zealand of Bayer HealthCare Business Group. APPA's Vice President is Dr Brian Muller. Congratulations to both! Coopted member of the IFAPP Executive Committee from Australia is Dr Sander Becker, who has been chairing the IFAPP Working Party on Ethics (WPE) since its inception in 2001.

IFAPP

IFAPP's Vision Statement

IFAPP's Vision Statement

The IFAPP Executive Committee agreed in its 12 April 2006 meeting on the following 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."

Frequently Asked Questions

TRIPS & pharmaceutical patents: fact sheet

The World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.

The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement. Details on this are available at:

www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm in the internet.

What is compulsory licensing?

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property – the TRIPS (Tra-

de-Related Aspects of Intellectual Property Rights) Agreement. Details on this are available at:

www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm in the internet.



Dates & Deadlines

28 February – 2 March 2007 • Bethesda, Maryland, U.S. FDA's Pharmaceutical Quality Initiatives – Implementation of a Modern Risk-Based Approach

This workshop is a follow up to the Workshop on 'A Drug Quality System for the 21st Century' held by the U.S. 'Product Quality Research Institute' (PQRI) and the U.S. 'Food and Drug Administration' (FDA) in April 2003. It is being planned under the auspices of the 'Council on Pharmaceutical Quality' at FDA and is co-sponsored with the 'American Association of Pharmaceutical Scientists' and the 'International Society of Pharmaceutical Engineers'.

The 2-1/2 day program is intended to present progress on FDA's pharmaceutical quality initiatives. Furthermore, the workshop will allow regulated industry, other stakeholders, and the public to comment on progress made and to provide input to facilitate implementation of a common vision for pharmaceutical manufacturing in the 21st century. Among topics to be addressed: pharmaceutical development, chemistry manufacturing and controls (CMC), manufacturing and quality operations, good manufacturing practices (GMP), quality systems, and quality assurance. Detailed information is available in the worldwide web at www.fda.gov/cder/gmp/pqi-2007.htm

15-16 March 2007 • Cologne, Germany 23 Annual DGPharMed Congress – 'German Society of Pharmaceutical Medicine – Deutsche Gesellschaft für Pharmazeutische Medizin e.V.' (DGPharMed)

Proposed main topics of the annual meeting are current issues of clinical research in phase III and IV. Clinical trial endpoints from the perspectives of clinical researchers, medical societies and governmental bodies also will be an important focus. Additionally, the status quo of pharmacoepidemeology, registries, comparative drug research, postmarketing surveillance studies are suggested topics for inclusion.

Detailed information is available at www.dgpharmed.de in the worldwide web

20-24 April 2007 • Seattle, Washington, USA 31st Annual ACRP Global Conference and Exhibition – 'Association of Clinical Research Professionals' (ACRP)

In 2007, the 'Academy of Pharmaceutical Physicians and Investigators' (APPI) will hold its next annual meeting and focused Program for Pharmaceutical Physicians and Physician Investigators as part of the ACRP Global Conference & Exhibition in Seattle, WA.

"The goal of this conference is to enhance the knowledge and skills of ACRP's membership in the conduct of clinical trials in order to evaluate the drug, biologic, and/or medical device's safety and effectiveness in treating, preventing or diagnosing a specific disease or condition. In addition to providing clinical research education and training, this conference acknowledges the dedication and excellence of its membership."

Detailed information is available at www.acrp2007.org in the worldwide web.

22-25 April 2007 • Amsterdam, The Netherlands Pharmaceutical Science World Congress – PSWC 2007

3rd World Congress of the Board of Pharmaceutical Sciences of the 'International Pharmaceutical Federation' (FIP) – Optimising Drug Therapy: An Imperative for World Health

"The PSWC 2007, co-sponsored by many of the world's leading pharmaceutical scientific and educational organizations, will cover a broad spectrum of topics from basic to applied and clinical sciences, addressing timely issues of great importance to drug discovery, development, regulation, and medication management. PSWC 2007 will also feature

interactive round table discussions, public debates, poster sessions, an exhibition, and will devote significant attention to the future generation of pharmaceutical scientists through poster and podium presentations, as well as a pre-conference meeting for graduate students and post-doctoral fellows." Dr Daan J. A. Crommelin, Chair of the Organizing Committee, on behalf of the PSWC 2007. Detailed information is available at www.pswc2007.org in the worldwide web.

29 August – 1 September 2007 • Amsterdam, The Netherlands 8th Congress of the 'European Association for Clinical Pharmacology and Therapeutics' (EACPT)

"The profession of clinical pharmacology is becoming increasingly important today. Clinical pharmacologists provide professional services to the pharmaceutical industry to enable the swift development of new drugs that benefit patients, and many of them are employed by this industry. They also provide professional services to other important organizations, such as drug regulatory authorities. All these important aspects of clinical pharmacology and pharmacotherapy and many new developments, especially those related to the conference theme of 'patient tailored pharmacotherapy', will be presented at this EACPT conference in Amsterdam." Chairperson Professor Jan H.M. Schellens, the Netherlands Cancer Institute, on behalf of the Organizing Committee.

Detailed information is available at www.eacpt2007.nl in the worldwide web.

7-10 September 2008 • Amsterdam, The Netherlands 15th 'International Conference on Pharmaceutical Medicine' - ICPM 2008

The theme of ICPM 2008 – supported by the Netherlands' authority – is 'Developing Pharmaceutical Care: Medicines after the Blockbuster Era.'

On behalf of the 'Netherlands Association of Pharmaceutical Physicians' (NAPP; www.nvfg.nl), IFAPP and the Chairperson of the Organizing Committee, Dr Rudolf van Olden, would like to welcome you to the ICPM 2008 in Amsterdam!

For ongoing information the official ICPM 2008 website has already been set up at www.icpm2008.org where you can order an ICPM 2008 newsletter to keep up to date.

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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Beyond the Horizon

Abridged Reports from ICPM 2006 - Seoul, Korea, September 3rd-6th, 2006 -

Report on Session A Clinical Trials: Experiences in the Emerging Markets

Chair: Ross Horsburgh (Singapore). Co-Chair: Tsutae Nagata (Japan). Speakers: Jorge Puente (Asia): Clinical Trials in Asia; George Chen (China): Clinical Trials in China; Daniel Mazzolenis (Argentina): Clinical Trials in Latin America; Gerfried Nell (Austria): Clinical Trials in Eastern Europe

For decades, new drug clinical development sponsored by internationally active pharmaceutical companies tended to focus on "traditional" regions, i.e., North America, Western Europe and Japan, reflecting market size. However, since the 1990s it has become obvious that trial site capacity in these regions is limited, with protracted recruitment time periods and costs too high for rapid big market access. At the same time, regulatory authorities requirements have been increasing.

Therefore 'emerging' markets in Latin America, Eastern Europe, and Asia, especially China, have become key centers for clinical drug development.

Success stories

Placing clinical trials in these regions proved to be a success story because all three regions provided: fast and high recruitment rates, special (untapped) populations availability, highly motivated investigators and patients, regulations compatible with ICH-GCP (ICH - International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use; GCP -Good Clinical Practice) and US FDA (Food and Drug Administration of the USA), good data quality and lower cost than in 'traditional' countries. Within this context, additional points that must be considered as part of clinical trial site suitability are: experience level of the individual investigator, logistics and transportation issues, communication infrastructure, health authorities attitudes and customs regulations, as well as English language fluency.

Clinical trial development is most advanced in Eastern Europe where 10% to 20% of all pharma-related clinical trials are now performed. Latin America follows with approximately 5%. Asia represents the largest potential, especially in India and China.

Professor Dr Gerfried Nell, IFAPP's President Elect, Austria



The Korean Smile. From left to right: Dr Yil-Seob Lee, Chairperson of ICPM 2006 Organizing Committee; Dr Yoon-Koo Kang, Professor of Medical Oncology and the Director of the 'Clinical Trial Center of Asan Medical Center', the biggest Medical Center in Korea; Dr Sang-Goo Shin, Professor of Clinical Pharmacology/Pharmacology, Seoul National University College of Medicine and Director 'Clinical Research Institute/SNUH'; Dr Deborah Chee, Secretary General ICPM 2006

Report on Session B Clinical Trials: Opportunities and Challenges in Asia

Chair: Jennie Sykes (UK). Co-Chair: Kihito Takahashi (Japan). Speakers: Kazuhiko Mori (Japan): The era of the multinational clinical trials including the Asian Area; Greg Voinov (France): Clinical trials in Asia-Social and Cultural Aspect; Frank Fan (China): Conducting Clinical Trials in Asia-Human Resources in Asia

The first speaker, Kazuhiko Mori, emphasized the commitment of the Japanese 'Pharmaceuticals and Medical Devices Agency' (PMDA) to be more open to bridging studies and as a result, play a more active role in global drug development. To facilitate this, the PMDA is organizing consultations where multinational trials can be discussed. The top three therapeutic domains of concern are: cancer, cardiovascular and neuropsychiatry.

Additionally, the PMDA has to take into account that some aspects typical of the Japanese population are rarely seen in the West, including the fact that many patients are older than 80 years and have a body weight of less than 40 kq.

The second speaker, Greg Voinov, stressed both the advantages and challenges of doing

clinical trials in Asia. The advantages are well publicized: fast recruitment, high quality of data, cost effectiveness and government support to name just a few.

Tolerant to local mindsets

However, these advantages are somewhat counter-balanced by the socio-economic, cultural, intellectual property and political challenges. Also differences in drug responsiveness must not be forgotten.

Greg Voinov concluded that when doing clinical trials in Asia one should be page 7



Dr Jennie Sykes, The United Kingdom, at Session B

◀ tolerant of the local mindset, understand the social system, accept cultural differences and plan everything well in advance.

The third speaker, Frank Fan, focused mainly on China, a country increasingly coming into focus in recent years. The advantages are evident: fast recruitment, huge market, lower costs, and high quality of the work performed. However, due to the fast evolution, there is a shortage of well-trained personnel. The speaker ended his talk by presenting the Clinical Trial Center of the University of Hong Kong as a case study.

Professor Dr Jean-Paul Deslypere, member of IFAPP's Executive Committee, Singapore

Report on the Special Session Pharmaceutical Medicine in Asia - Today and Tomorrow

Chair: Churl J. Kim (Korea). Speakers: Kenneth Hartigan-Go (Philippines), Kyoko Imamura (Japan), Ahmad Atif Mirza (Pakistan), Paul Jang (Korea), Jean-Paul Deslypere (Singapore), Sunettra Chinnapha (Thailand), Frank Fan, Frank Yuan (China), William Huang (Taiwan)

After an introduction by the new President of IFAPP, Dr Luis Collia, representatives of different Asian countries presented the current status of Pharmaceutical Medicine in their respective countries.

In some countries (Philippines, Japan, Pakistan, Korea, Indonesia) an Association of Pharmaceutical Medicine has existed already for many years, while in other countries it has just been set up (Singapore) or is in the process of being created (Thailand, China, Taiwan).

Importance of Pharmaceutical Medicine increases

The recognition of Pharmaceutical Medicine as a specialty remains a problem in many

countries and sometimes there even is no obligation for the pharmaceutical industry to employ a medical doctor. The lack of specific training as a pharmaceutical physician was a concern for many presenters.

In most countries, professionals engaged in clinical research are active in teaching and training, organizing conferences and workshops and enhancing the clinical research quality. Regular interactions with regulatory authorities and academia are seen as equally important.

It was the general consensus of all speakers that pharmaceutical physicians are now playing an increasingly important role in the pharmaceutical industry at many different levels, therefore making the need for appropriate training and certification in Pharmaceutical Medicine more relevant than ever before.

Professor Dr Jean-Paul Deslypere, member of IFAPP's Executive Committee, Singapore

Report on Session C Ethics in Pharmaceutical Medicine

Chair: Sutinder Bindra (AP). Co-Chair: Paul Jang (Korea). Speakers: Jane Barrett (UK): Ethics in Biomedical Research; Pol Vandenbroukke (Japan): Ethics in Pharmaceutical Business Practice; Ock-Joo Kim (Korea): Ethical Issues in Stem Cell Research: Experience in Korea

Ethics in Biomedical Research

Transparency and truth were the themes of this excellent presentation. Within this framework, "informed consent," "free will," "the rights" and "protection" of both the patients and doctors involved in medical experimentation were addressed.

Jane Barrett directed the audience's immediate attention to historical codes relating to medical scientific practice. It was interesting



At ICPM 2006 registration desk



Dr Jane Barrett, IFAPP Executive Committee member from The United Kingdom, at Session C

to note that the First Prussian Directive on informed consent preceded the Nuremberg Code of 1947.

The presenter then mapped out the path for medical researchers and explained its implications - from the Hippocratic oath through to the Declaration of Helsinki, then CIOMS (Council for International Organizations of Medical Sciences), ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use), the WHO (World Health Organization) 'Good Clinical Practice' and the European Union 'Clinical Trial Directive 2001/20/EC'. Jane Barrett explained that patients' rights when taking part in research are also protected under the International Bill of Rights, the International Covenant on Civil and Political Rights - which states that "no one shall be subjected to torture or cruel, inhuman, or degrading treatment or punishment."

An ethical guideline for research involving humans is founded on four principles: beneficence (people can expect that doctors have a duty to do good things to their patients), nonmaleficence (patients will not be deliberately harmed by their doctor), autonomy (adults of sound mind have a right to decide what happens to their bodies) and justice (everyone has rights to have medicines tested for them and on them).

The presenter then gave a number of scientific and legal examples that introduced ethical questions, which investigators participating in clinical research need to consider.



Take home message: The rights of human research protecting the rights of the child, the elderly and the disabled need to be carefully evaluated.

Dr Sander Becker

Ethics in Pharmaceutical Business Practice

Pol Vanderbroucke provided a brief historical perspective spanning from the 'Hippocratic oath' through the 'Declaration of Helsinki' and 'International Federation of Pharmaceutical Manufacturers' (IFPMA) Promotional Code. The speaker highlighted that most pharmaceutical industry employers are well aware of company business "credo" and "values". However, they are not provided with general business ethics know-how or ethical guidelines. Also "systematic training in ethics" is not provided.

The speaker posed a provocative question: "Do we need ethical guidelines?" He believed that they are as important as company culture, business performance, industry and company regulations and legal advice. Clinical research ethics codes are developed and continue to evolve, while business ethics and other aspects of the pharmaceutical industry are less well developed.

Take home message: Business needs to take responsibility for training their employees by establishing ethical guidelines or business codes will need to be introduced.

Dr Sander Becker

Ethical Issues in Stem Cell Research: Experience in Korea

Detailing the Huang Woo-Suk cloning stem cell scandal that rocked the world's scientific community, Ock-Joo Kim of Seoul National University, Korea, gave a fascinating presentation. Huang's paper had been hailed as a breakthrough, opening the possibility of degenerative diseases cures. He was hailed as a hero until it became evident that the so-called stem cell colonies had been faked.

The speaker impressed the audience with her candor. She gave the background on when the fraud being first suspected and then proven, including the investigations that had taken place in the research center, outlining her involvement in the process. Ock-Joo Kim spoke of the furious South Korean media debate initiated by the revelations and of her anger that a respected scientist published work he knew to be false.

The speaker said that the controversy is still raging in the Korean scientific community, with some feeling that it was unpatriotic to challenge someone who had given the country a lead in such a promising new area. Indeed, some companies withdrew advertisements from the television station that first revealed the problems with Huang's work.

Take home message: All scientific breakthroughs must be rigorously tested and reproduced before they can be considered true advances. In this respect nobody is above the law or above suspicion. Science must also be ethical and truthful. *Dr Jane Barrett*

Report on Session D How to Improve Access to Medicine

Chair: Bong-Min Yang (Korea). Co-Chair: Stephen Phua (Singapore). Speakers: Zili Li (USA): Improve Access to Medicine – What We Can Learn From US FDA Clinical Review Practice; Criscuolo Domenico (Italy): Pricing and Reimbursement; Johanna Schenk (Germany): Informed Patients

Access to medicines depends on market availability and affordable cost. In countries with a socialized health care system the drug reimbursement reduces the patients' co-payment.

Three presentations considered access to medicines, each from a different angle. Zili Li highlighted that recently a US Food and Drug Administration (FDA) clinical review practice attempted to bring effective and safe drugs sooner to the general public. Regulatory agencies in other regions have to find out if these good review practices are applicable in their markets. The second speaker, Criscuolo Domenico, discussed pricing and reimbursement, which is still regulated by national health services in most countries of the European Union (EU), while in Japan and the US there is a free market approach. Hence prices and reimbursement in the EU are based on a cost-effectiveness evaluation and reference price system, comparing individual price of any new drug against the prices of similar drugs within the same class that are already available for the same indication.

Informed patients

Experts expect increasing price pressure on new 'expensive' drugs, unless these new drugs are seen as truly 'innovative' or orphan drugs. This economic pressure will be a barrier to new drugs access. In her presentation on 'informed patients,' Johanna Schenk outlined that drug information is shifting away from paternalism to partnership. However, although not all patients can be reached, the majority should benefit when well informed.

Well-informed patients are less anxious, start their treatment earlier, follow their doctor's advice more closely, and are capable of self-management and more efficient in searching for adequate resources. Better-informed patients also avoid or minimize the risk of adverse reactions and interactions. This may result in a drop in health care costs.

Additionally, patients can provide a unique perspective on the importance of innovative drugs and state with authority the balance that should be struck between benefits and risks. To facilitate this, pharmaceutical professionals and physicians have a vital role in a concerted action together with prescribing physicians, clinical investigators, regulators and patient organizations.

Dr Henri Pintens, Belgium

Report on Session E Pharmaceutical Medicine

Chair: Henri Pintens (Belgium). Co-Chair: Churl J. Kim (Korea). Peter Stonier (UK): Pharmaceutical Medicine as a Specialized Discipline of Medicine; Madeleine Billeter (Switzerland): Pharmaceutical Medicine Specialization in Europe: Is the Model Exportable Elsewhere? Kyoko Imamura (Japan): Development Pharmaceutical Medicine Specialty in Asia



Dr Churl J Kim, Korea, and Dr Henri Pintens, Belgium, co-chairing Session E



"Over 30 years Pharmaceutical Medicine has developed as a medical scientific discipline for the discovery, development, evaluation, registration, monitoring, and medical marketing of medicines for the benefit of patients and community health," Peter Stonier, the first speaker, said. Pharmaceutical Medicine is well established in many countries among other medical specialties and has accumulated a distinct body of knowledge, based primarily on clinical science. Peter Stonier noted that Pharmaceutical Medicine is a listed medical specialty in Switzerland, Mexico, Philippines, UK and Ireland, where its recognition is underlined by accredited education and training.

Swiss model of Pharmaceutical Medicine

The second speaker, Madeleine Billeter, explained how Pharmaceutical Medicine became recognized as a medical specialty in Switzerland and implemented since 1999. Continuous Medical Education is part of the new Swiss law on therapeutic products, and is considered a life-long task. The speaker concluded that the Swiss model certainly could be transferred to other countries.

Although Pharmaceutical Medicine has been recognized in Japan for a short time only and education and training have not yet been harmonized, there are ongoing efforts in order to establish consensus among various bodies to promote this discipline and to develop common standards, said Kyoko Imamura, the third speaker. The goal is to establish a process for continuous professional development and a broad recognition of Pharmaceutical Medicine.

Dr Mirela Barbu, member of IFAPP's Executive Committee, Switzerland



Manning the IFAPP Booth – Dr Mirela Barbu, IFAPP Executive Committee member from Switzerland

Report on Session F New Initiatives in Pharmaceutical Medicine Training

Chair: Rick Sax (USA). Co-Chair: Chris Bruenger (Japan). Carl David Sundstedt, (Sweden): In-House Education in Pharmaceutical Medicine for Physicians and Scientists – the AstraZeneca Experience; Sree Haran (UK): GSK Academy: a 'Centre of Excellence' in Pharmaceutical Medicine; Honorio Silva (USA): Pfizer Development Program

The AstraZeneca Experience

The so-called AstraZeneca Experience, described by the first speaker Carl David Sundstedt, centers on a Medical Education Group (MedEd). Created as a strategic-planned global medical education program in order to develop physicians and other professionals in Pharmaceutical Medicine, it originates from 1999, the year of the Astra and Zeneca merger. Its goal was to offer learning opportunities of high relevance and quality, including in-house courses or seminars and web-based 'ambulatory' learning programs. The original target group was AstraZeneca's medical doctors, but later it expanded to clinical researchers, drug safety experts and other people working for the pharmaceutical company. The teachers came from a number of different countries.

Since inception, MedEd teams have created more than 80 programs and delivered it to over 4,400 participants on four continents.

The MedEd website provides a library of presentation material from past learning programs, including access to digital video and audio recordings of all courses and from monthly seminars held at the R&D sites. It also contains sections with pertinent news items and links to external Pharmaceutical Medicine and regulatory sites, which recorded almost 13,000 visits in 2005.

The speaker showed the pros and cons of live courses versus distance learning programs, highlighting the challenges of recruitment new members, updating materials and rewarding ailments.

GSK Academy

The second speaker, Sree Haran, explained how the GlaxoSmithKline (GSK) Academy recently established a 'Center of Excellence' in the specialty. It functions as a virtual network under the supervision of a Postgraduate Medical Director. The majority of the faculty comes from within the different line departments, which gives a culture of empowerment and ownership. The speaker claimed that the rapid development of Pharmaceutical Medicine as a specialty could be facilitated by the active participation of various stakeholders (external ones) and pointed out that the establishment



ICPM 2006 Busy Coffee Break

of 'Academies' of Pharmaceutical Medicine could be a business model to warrant further consideration (GSK).

The objectives would be not only to educate physicians in Pharmaceutical Medicine and to brand Pharmaceutical Medicine as an entity or specialty, but also to institutionalize Pharmaceutical Medicine as a global venture within GSK by launching a curriculum in Pharmaceutical Medicine comprising 58 sessions of 15 modules with more or less 180 assistants.

e-learning: Pfizer's academic training

Honorio Silva, the third speaker, emphasized an internet-based e-learning approach, which "appears to be as effective as conventional medical education in producing objectively measured changes in behavior as well as sustained gains in knowledge, with the advantages of flexibility and lack of geographical boundaries." This indeed is required, as a needs assessment process among the Pfizer medical and regulatory personnel clearly demonstrated.

As a result, Pfizer developed a Pfizer-independent, blended web based Master of Science program, offering an innovative and unique opportunity for Pharmaceutical Medicine academic training by reaching real need effectiveness. It is based on IFAPP's curriculum and the curriculum of the 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians' of the United Kingdom, accredited through the 'Higher Education Training and Awards Council' (HETAC) of Ireland. This program leading to a Master of Science in Pharmaceutical Medicine qualification is composed of ten modules delivered over two years, including two live oneweek seminars, eight asynchronous on-line



lessons with weekly synchronous tutorials and the completion of a research project. It is distributed in 16 weeks per module with seven hours per week with periodic meetings. The speaker noted that the 2005 class included 45 Pfizer employees in 23 different countries.

Although the program is now open to all colleagues in the pharmaceutical industry, the success of the first year has led to the creation of a second exclusive Pfizer class in 2006. "This is an example of innovative partnership to provide value in graduate education," the speaker concluded.

Dr Luis Francisco Collia, President of IFAPP, Argentina

Report on Session I Cutting Edge Technology in Drug Development

Chair: Mark A Bach (USA). Co-Chair: Dong-Ho Lee (Korea). Speakers: Joong Myung Cho (Korea): Accelerating Drug Discovery Based on Structural Chemo Proteomics; Yasuhiro Hashimoto (Japan): Identification of Novel Drug Target Utilizing Genomics, Proteomics and In Silico Technologies; Richard Hargreaves (USA): Imaging in Drug Discovery and Development

This session focused on recent technological innovation. The first speaker, Joong Myung Cho, reviewed the technology named 'Structural Chemo Proteomics' (SCPTM) and the way in which an integrated platform utilizing computer screening and nuclear magnetic resonance can now determine the three-dimensional structure of disease target proteins such as phosphodiesterases, kinases and proteases. Once the three-dimensional structure is known, it is possible to manufacture drug candidates using x-ray crystallography and combinatorial chemistry. One example of such a candidate is a COX-2 inhibitor potentially lacking vascular or renal side effects, owing to a dual action on carbonic anhydrase and COX-2.

Yasuhiro Hashimoto, the second speaker, expanded on this theme, describing how integrating data from genomic, proteomic and metabolomic sources by bioinformatics allows drug target molecules to be identified more rapidly. Gene and protein expression in disease also may be used to predict the biological and signaling pathways involved, although it is fair to say that array data expression may result in complex pathways, which mandate enrichment analysis. These pathways can be tested by the effect of probe drugs in mechanistic models.

The third speaker, Richard Hargreaves, described the role of imaging in drug discovery and development. The external climate is favorable to biomarker toolbox development, which also includes imaging. However, it is



Advertising 'IFAPP World' at the General Assembly – Dr Christopher Allen, The United States, IFAPP Immediate Past-President

important to recall that for biomarkers, innovation is inversely proportional to validation. Investment is needed in biomarkers before the availability of suitable drug candidates can develop. Imaging can be applied to many therapeutic fields:

- 1. In the cardiovascular arena fresh atheromatous plaque can be collected for biomarker analysis. Pre dose and end of dose samples allow the effect of therapeutic intervention to be assessed. Furthermore, non-invasive Multi-Slice CT can detect coronary calcification, and plaque can be imaged using fluorodeoxyglucose uptake.
- 2. Respiratory imaging using hyperpolarized noble gases can outline lung airways, allowing ventilation mapping and assessment of diffusion coefficients. This technique has excellent translational potential to the clinic.
- **3.** In oncology the degree of fluorodeoxyglucose uptake has been a predictor of longterm survival in stromal tumors.
- **4.** Neurological imaging uses Positron Emission Tomography (PET) and Magnetic Resonance (MR) techniques along with selected ligands in four main ways:
- 4a) mapping neuroreceptor distribution to identify the involvement of specific neurotransmitters in CNS disease and investigate drug binding to these receptors
- 4b) structural and spectroscopic imaging to examine morphological changes and the consequence of such changes

- 4c) metabolic mapping to provide evidence of central activity and clarifying the neuroanatomy of drug effects (e.g., imaging the 'migraine generator')
- 4d) functional mapping to examine disease drug interactions.

Dr Christopher Allen, Past President of IFAPP, United States of America ■



Dr Luis Franscisco Collia, IFAPP President, Argentina, with an address at the Gala Dinner



IFAPP News

Poll amongst IFAPP's national Member Associations

High Importance of IFAPP's Code of Ethical Conduct

As previously reported in IFAPP World I/2006, IFAPP has recently conducted a poll among IFAPP's national Member Associations on IFAPP services and communication as well as Pharmaceutical Medicine ethics. Out of the then 29 national Member Associations, 18 responded (62%) completing the IFAPP's questionnaire: South Africa, Belgium, Switzerland, the United Kingdom, Italy, Korea, Greece, Ireland, Argentina, the Netherlands, Turkey, Australia, the United States, Brazil, Indonesia, Pakistan, Germany and one anonymous country. The results were generated in May 2006. Details regarding the subject communication were summarized in IFAPP World I/2006, July 2006 issue. In this issue the results on ethics in Pharmaceutical Medicine are provided.

The answers to the key question: "Please rank the importance of the current services that IFAPP provides" clearly demonstrate the high importance of the IFAPP's Code of Ethical Conduct relative to other IFAPP services (Figure 1). The Code of Ethical Conduct value is exceeded only by "education, accreditation and training in Pharmaceutical Medicine" and "assistance in establishing courses in pharmaceutical medicine."

On the question: "Does your National Association have a Code of Ethical Conduct?" 35% of respondents answered "yes" and 65% said "no." The "yes" answers were further specified with a share of 44% of the respective national Member Associations using the IFAPP's Code of Ethical Conduct. The remaining respondents

said a national authority like the Society of Chemical Industries, the Association of Pharmaceutical Physicians, the General Medical Council, the Pharmaceutical Industry Association or the Ministry of Health administered their code of ethical conduct.

Of national Member Associations using IFAPP's Code of Ethical Conduct, 78% said this Code is working well. However, there were several comments from poll participants on the question: "Which aspects need to be addressed and changed?"

"All members of the 'British Association of Pharmaceutical Physicians' (BrAPP) expected to abide by the 'General Medical Council's' (GMC) 'Duties of a Doctor'. However, IFAPP's Code mirrors GMC so not an issue for us."

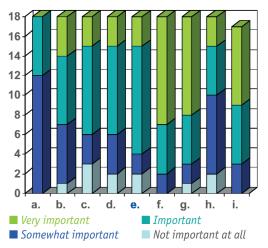
"We are discussing the opportunity to implement the IFAPP Code."

"We are moving to the side of working, but not well. It looks like to have discrepancy between multinational companies and domestic companies. The government is involved in its implementation."

"Charter is sufficient, and oath of Hippocrates."

Almost daily ethics in medicine, and particularly in pharmaceutical medicine, are being questioned and challenged. In this respect, another crucial question of IFAPP's poll was: "Has your National Association faced an ethical dilemma over the last five years?" Just 20% of respondents answered "yes" while 80% said "no" (Figure 2).

 $\textbf{\it Figure 1:} Importance of the Code of Ethical Conduct provided as a service by the IFAPP relative to other services - ranking by IFAPP's national Member Associations$



- a. pharmaceutical and country news
- b. international conference on Pharmaceutical Medicine
- c. conferences involving EMEA
- d. conferences involving FDA

e. Code of Ethical Conduct

- f. education, accreditation and training in Pharmaceutical Medicine
- g. assistance in establishing courses in Pharmaceutical Medicine
- h. assistance in establishing member associations
- i. promotion of recognition of Pharmaceutical Medicine as a medical specialty

Figure 2: Has your National Association faced an ethical dilemma over the last five years?

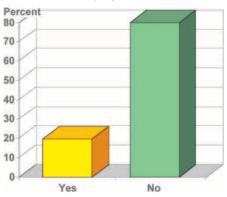
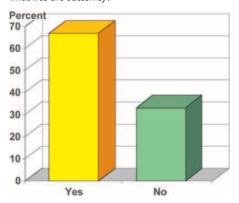


Figure 3:

If yes, would you be prepared to share the details in follow-up (what happened, how was it managed, what was the outcome)?

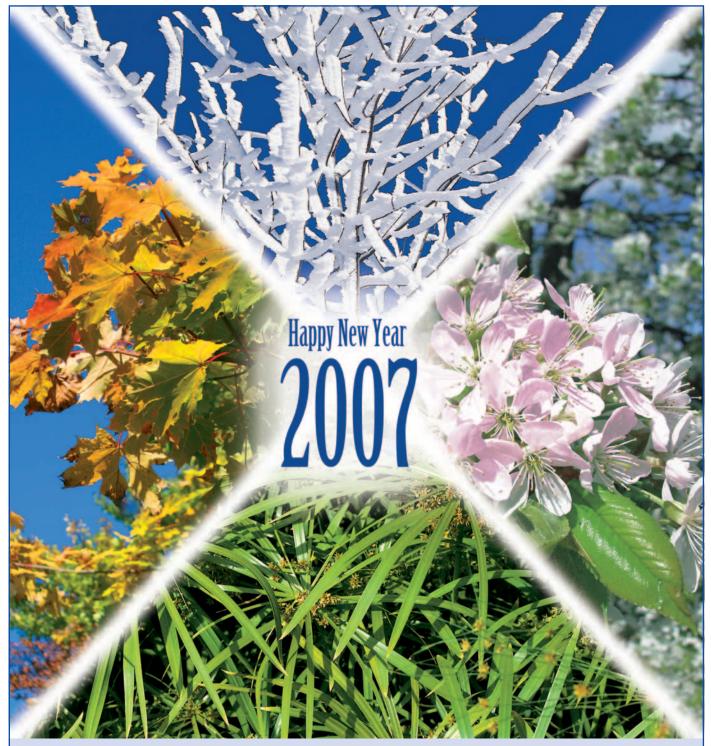


Roughly two-thirds (67%) of all poll participants stated, they would be prepared to share the details of any ethical dilemma in follow-up with reports on what happened, how was it managed and what was the outcome (Figure 3).

For further details you may like to visit the IFAPP's international "Working Party on Ethics" (WPE) web site (www.ifapp.org following "ethics" in the menu). Here you will find the WPE conclusion: "Ethics in pharmaceutical medicine is a vast subject. We hope that by working on this Code we may have begun the process of helping the transparent discussion of the issues it raises. We have no absolute answers but hope that the points we raise in the Code will stimulate others to consider in thoughtful depth the points raised." Get involved – you are cordially invited!

Eckhard Boettcher-Buehler





IFAPP and IFAPP World extend best wishes for a peaceful and pleasant holiday season and a prosperous New Year to our national Member Associations, our colleagues and friends worldwide.

The next 'IFAPP World' issue is coming soon:

Issue	Closing date	Publication date
IFAPP World No. 1/2007	14 March 2007	30 March 2007
IFAPP World No. 2/2007	20 June 2007	06 July 2007
IFAPP World No. 3/2007	19 November 2007	03 December 2007

Get involved and keep in touch with IFAPP – Contributions welcomed!

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