IFAPP WORLD
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International Federation of Associations of Pharmaceutical Physicians
III·2007·DECEMBER

CONTENT

IFAPP's Calendar

ICPM 2008 in Amsterdam

Developing Pharmaceutical Care – Medicines After the Blockbuster Era

Just nine months to go before the opening of the next 'International Conference on Pharmaceutical Medicine 2008' in Amsterdam, the Netherlands, 7-10 September 2008! Registration is open now at www.icpm2008.org where you also will find the latest news, the most up-to-date scientific program, call for abstract details and accommodation information as well as social activities during the conference.

Why should you come to the ICPM 2008 in Amsterdam?

This conference is your biannual 'vaccination' to enrich your practical knowledge on different key topics in Pharmaceutical Medicine – this conference is specifically designed to address all of the related aspects in our current changing environment. For scientists and colleagues working in the clinical operations field there also is an interesting parallel program which takes as a starting point the overall congress theme "Developing ▶ page 2

President's Letter

Dear Colleagues

Dr Luis F. Collia, IFAPP President

During IFAPP's face-to-face October Executive Committee meeting in London, we reviewed our achievements, analyzed ongoing initiatives and discussed our future plans. Delegates from ten countries and two co-opted members were present. Specifically, we developed a draft for IFAPP's future Strategic Plan, which will be discussed at the next meeting; we reviewed the financial figures for 2007 and estimates for 2008, updated the ICPM 2008 strategy and determined the 'Ethics Working Group' perspectives.

On 19 October, the 9th IFAPP European Conference took place, organized in collaboration with the 'British Association of Pharmaceutical Physicians' (BrAPP). The excellent speakers focused on "The Impact of the EU Directive on Clinical Trials" in the morning session and on "The Emerging Role of Europe in Pediatric Development" in the afternoon session. A total of 40 enthusiastic attendees took an active, participating role during the conference. ▶ page 2

Questions & Answers

Set up the 'Chinese Society of Pharmaceutical Medicine'

The 'First Chinese Conference on Pharmaceutical Medicine' (CCPM 2007) was held in Beijing on 18-20 October 2007 and was both a milestone event and huge success, as Dr Frank Fan, Representative and Co-Founder of the 'Chinese Pharmaceutical Medicine Forum' (CPMF) reports on page 2. What is the idea behind CCPM 2007, what was the plan and what is the perspective? Dr Fan has answered these questions in a conversation with Eckhard Boettcher-Buehler from IFAPP World.

Dr Frank Fan: "Thanks to the active support and encouragement from both CMA and IFAPP, the first 'Chinese Conference of Pharmaceutical Medicine' (CCPM 2007) successfully became a true milestone for Pharmaceutical Medicine in China."

IFAPP World • Dr Fan, you and the other organizers obviously raised intense interest with CCPM 2007 – congratulations. Was it purely participants' interest in conference program content or were they also interested in the plan to establish a 'Chinese Society of Pharmaceutical Medicine'?

Dr Frank Fan • China is becoming one of the most dynamic pharmaceutical markets in the world. Both, multinational pharmaceutical companies and local start-up life science biotech companies are setting up or expanding their research and development facilities in China.

The number of physicians joining the pharmaceutical industry has been increasing dramatically in the past few years. They are involved in almost all activities concerning Pharmaceutical Medicine, such as ▶ page 3

President's Letter

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Another important meeting was held at the same time on the other side of the globe: the first 'Chinese Conference on Pharmaceutical Medicine', Beijing, China, 18-20 October 2007. IFAPP was represented by Professor Jean-Paul Deslypere from Singapore, Professor Gerfried Nell from Austria, and Professor Peter Stonier from the United Kingdom. As Dr Frank Fan, Representative of the 'Chinese Pharmaceutical Medicine Forum' (CPMF) reports on this page, the conference had more than 400 attentive and enthusiastic participants, most of them physicians and experts in Pharmaceutical Medicine. As Professor Nell confirmed, the program covered the whole area of Pharmaceutical Medicine with lectures of the highest international standard. Details on the initiative to set up the 'Chinese Society of Pharmaceutical Medicine' you can find in an interview with Dr Fan, beginning on the previous page.

During my European tour prior to the 9th IFAPP European Conference, I met Executive Committee (EC) members of different national member associations (nMAs) in London at the conference venue and in Paris and Budapest. These individual meetings with colleagues have strengthened the relationship between IFAPP and nMAs. I would like to thank all who attended and made these meetings possible; thank you for your support and hospitality. I hope to meet EC members from other countries in the future in order to learn more from their opinions and suggestions that would benefit IFAPP as a global network. All of you are kindly invited to work with the EC in regional and international tasks, in order to reach IFAPP's objectives and to get the recognition and visibility that we seek.

With regard to ICPM 2008, you already can register for the event, send abstracts and book hotels and tours. A preliminary program is available at www.icpm2008.org and you will soon find it completed with names of the chairmen and speakers. With regard to ICPM 2010, I invite you all to analyze the possibility of your region hosting this important event and of course, if you decide to take this challenge, please send a proposal to IFAPP's secretariat (ifapp@planet.nl).

Last but not least, it is my pleasure to congratulate the newly elected presidents of the Australian Society, Dr Leanne Wall, and of the Spanish Society, Dr José Maria Giménez-Arnau, who recently assumed these positions. Finally, I thank all of you for your active participation in IFAPP's operations and wish you all a Happy New Year 2008!

Dr Luis Francisco Collia, IFAPP President, Medical Manager Merck Serono Argentina, Buenos Aires, Argentina ■

IFAPP's Calendar

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Pharmaceutical Care; Medicines after the Blockbuster Era."

In addition to the scientific program, there will be three parallel 'executive training modules' (free of extra charge!) during the morning session: 1. Statistics for non-intervention studies, 2. Update in risk management planning, 3. Media training for pharma executives. You can click the button on your online registration form to have a chance to participate in these executive classes! As there is limited capacity, participation is on a first-come basis through online registration and payment.

As well as the scientific program, there will be an interesting Welcome Reception in the Rijksmuseum and an unforgettable Dutch Gala Dinner in the Beurs of Berlage. All activities take place around the center of Amsterdam.

Dr Rudolf van Olden, Member of IFAPP's Executive Committee, Chairperson ICPM 2008 on behalf of the local organizing and scientific committee ■

Join ICPM 2008 in Amsterdam!

Reports & Concepts

First 'Chinese Conference on Pharmaceutical Medicine': a Milestone Event

Dr Frank Fan, Representative and Co-Founder of the 'Chinese Pharmaceutical Medicine Forum' (CPMF), Beijing, China

China • The first 'Chinese Conference on Pharmaceutical Medicine' (CCPM 2007), held in Beijing on 18-20 October 2007, was a milestone event and big success. Its key focus was to promote Pharmaceutical Medicine as a medical specialty in China.

Since the late 1980s, China has emerged as a dynamic pharmaceutical market. Many global R&D based pharmaceutical companies started setting up their affiliate operations in China, and increasingly medical doctors have been joining the pharmaceutical industry in the fields of clinical research, medical affairs, regulatory affairs and pharmacovigilance. Overall, Pharmaceutical Medicine is recognized in China progressively more as a medical specialty.

CCPM 2007 was jointly organized by the 'Chinese Medical Association' (CMA), the 'Chinese Pharmaceutical Association' (CPA) and the 'Chinese Pharmaceutical Medicine Forum' (CPMF) in collaboration with IFAPP. Its program was diverse and in-depth, covering most aspects of Pharmaceutical Medicine and including 10 themes, 33 presentations, four featured seminars, three panel discussions and a pre-conference workshop on clinical research methodologies.

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The CCPM 2007 Organizing Committee and guests at the closing ceremony

Questions & Answers

◀ page 1 exploratory development, clinical trials, post-marketing studies, pharmacovigilance, medical marketing and pharmacoeconomics, and so on. Pharmaceutical Medicine has become an often-mentioned topic among the pharmaceutical R&D professionals, however it is far from being officially and widely recognized as a distinct medical specialty in China.

In 2003, a group of physicians working in the pharmaceutical R&D departments in multinational pharmaceutical companies formed an organization named 'Chinese Pharmaceutical Medicine Forum' (CPMF) to promote Pharmaceutical Medicine as a medical specialty. In the past four years, with energetic support from the 'Chinese Medical Association' (CMA), an official national organization of professionals in the field of medical science, CPMF has organized various conference and seminars, published newsletters and collaborated with other academic organizations to both enhance Pharmaceutical Medicine and improve the visibility and influence of pharmaceutical physicians in China.

Thanks to the active support and encouragement from both CMA and IFAPP, the first 'Chinese Conference of Pharmaceutical Medicine' (CCPM 2007) successfully became a true milestone for Pharmaceutical Medicine in China. Pharmaceutical Medicine is now being known and understood by more and more pharmaceutical R&D professionals as a medical specialty. As agreed by the CMA leaders, the process of establishing the 'Chinese Society of Pharmaceutical Medicine' has started.

IFAPP World • Regarding your Pharmaceutical Medicine initiative in China: What actions do you plan on national and international levels?

Dr Frank Fan • Although widely known as an interlink subject between clinical medicine and pharmaceutical science, Pharmaceutical Medicine has not yet been recognized officially by the academics and regulatory authorities as a distinct medical specialty in China. Currently there is no official postgraduate educational program for Pharmaceutical Medicine here. Following the successful CCPM 2007, we will be working with CMA and IFAPP to set up the CME/CPD schemes to improve the training and education of pharmaceutical physicians, based on the guidance of IFAPP's 'Council for Education in Pharmaceutical Medicine' (CEPM), as the first step in the short term. For the next step in the medium and long term we will try to collaborate with medical and pharmacy schools to initiate a Postgraduate Course of Pharmaceutical Medicine.

In addition, there are a lot more initiatives in our minds; the key activities will include:

- Organize scientific conferences and seminars on a variety of issues concerning the discovery and development of pharmaceuticals, vaccines, medical devices and diagnostics.
- Publish newsletters and academic journals in the filed of Pharmaceutical Medicine.
- Improve the collaborations with other medical specialty societies and associations.

We also are planning to host the 'International Conference of Pharmaceutical Medicine' (ICPM) in China in the near future.

IFAPP World • Chinese experts in Pharmaceutical Medicine obviously are well organized already and participate in several institutions: the 'Chinese Medical Association' (CMA), the 'Chinese Pharmaceutical Association' (CPA) and the 'Chinese Pharmaceutical Medicine Forum' (CPMF). Could you briefly explain the differences between these organizations and how they would relate to a prospected 'Chinese Society of Pharmaceutical Medicine'?

Dr Frank Fan • The 'Chinese Medical Association' (CMA), founded in 1915, is an official organization of physicians and medical science professionals. Under CMA, currently there are 82 medical specialty societies, such as the 'Chinese Society of Internal Medicine', the 'Chinese Society of Clinical Oncology', and so on.

The 'Chinese Pharmaceutical Association' (CPA), founded in 1907, is an official organization of pharmaceutical scientists. Under CPA, currently there are 15 pharmaceutical specialty societies, such as the 'Society of Pharmacology', the 'Society of Hospital Pharmacy', and so on.

The 'Chinese Pharmaceutical Medicine Forum' (CPMF), affiliated to CMA, is a preparatory body of the 'Chinese Society of Pharmaceutical Medicine' (CSPM). Its members include pharmaceutical physicians and clinical research professionals.

IFAPP World • What are the next steps towards the 'Chinese Society of Pharmaceutical Medicine' and the recognition of Pharmaceutical Medicine as a medical specialty?

Dr Frank Fan • In the next few months we will be working closely with the 'Chinese Medical Association' (CMA) to set up the 'Chinese Society of Pharmaceutical Medicine' (CSPM). Its mission is to promote the awareness, visibility and influence of Pharmaceutical Medicine as a distinct medical specialty and help our pharmaceutical physicians to keep their knowledge and skills up to date throughout their professional careers. CSPM membership will include the pharmaceutical physicians and clinical research professionals who spend the majority of their time in matters related to Pharmaceutical Medicine.

CSPM will be built on the current organization and membership of the already existing 'Chinese Pharmaceutical Medicine Forum' (CPMF) and will become one of the 80 academic societies affiliated to CMA. Definitely, CSPM will apply to become member of IFAPP at the appropriate time. We are looking forward to keeping a close working collaboration with IFAPP and other national Pharmaceutical Medicine associations.

IFAPP World • Thank you very much. And all the best for making your initiative a success! ■

Reports & Concepts

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Representatives from the Chinese 'Ministry of Health' (MOH) and the 'State Food and Drug Administration' (SFDA), from CMA and CPA attended the conference. Mr Zhang Wei, Head of SFDA's department for drug registration, presented a keynote lecture on the development of innovative pharmaceuticals in China. Professor Gerfried Nell from Austria, delegate and President Elect of IFAPP, introduced IFAPP's mission and vision in the 21st century. While Professor Peter Stonier from the United Kingdom, Director of Education & Training of the 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom', gave a keynote lecture on Pharmaceutical Medicine as a medical specialty. Professor Jean-Paul Deslypere from Singapore, Chairman of IFAPP's 'Council for Education in Pharmaceutical Medicine' (CEPM), gave a lecture on the development of Pharmaceutical Medicine in the Asia-Pacific region. Dr Frank Fan, representative of CPMF, introduced the status and vision of setting up Pharmaceutical Medicine as a medical specialty in China.

The conference was well attended by more than 400 professionals coming from multinational and local pharmaceutical companies, contract research organizations, hospitals, academic institutions and regulatory agencies.

The conference closing plenary session culminated in a lecture by Professor Gerfried Nell on the career development of pharmaceutical physicians, which raised a lot of positive feedback from the attendees.

During the conference, delegates from IFAPP – Nell, Stonier and Deslypere – had meetings with the delegates from CMA and CPMF, discussing the perspective of setting up the 'Chinese Society of Pharmaceutical Medicine' in the near future. ■

Personal Snapshot

Dr Stewart Geary Decorated with DIA's 'Outstanding Service Award'

Dr Stewart Geary, Tokyo, Japan: "In Pharmaceutical Medicine we have the opportunity to help not just the patients we could physically see in a day at the clinic, but to change the practice of medicine and expand the treatment options for patients around the world."

Dr Stewart Geary's expertise in the fields of pharmacovigilance, clinical safety and regulatory science is in great demand internationally. Recently in recognition of his work, he received the 'Outstanding Service Award' from the 'Drug Information Association' (DIA). Indeed, Dr Geary has provided and continues to provide outstanding service through his excellent in-depth knowledge, giving valuable assistance to many international organizations involved in Pharmaceutical Medicine.

Dr Geary modestly describes it as admitting one's responsibility. Yet his concept of responsibility extends beyond drug safety common to the general public interest, to individual benefits for patients. Additionally, his unique perspective includes intuitive global thinking.

As recently announced in 'DIA today,' Dr Geary is currently a member of the CIOMS VIII Working Group on Signal Detection, the DIA Advisory Committee Japan, the Executive Committees of the 'Japanese Association of Pharmaceutical Medicine' (JAPhMed) and IFAPP and the Regulations Advisory Board for the CMR International Institute for Regulatory Science, as well as on the Editorial Advisory Board for 'Applied Clinical Trials' (ACT). He previously served as a member of the CIOMS VII Working Group on the Development Safety Update Report and the CIOMS Working Group on Standardized MedDRA Queries. He has had the pleasure of serving on program committees, as track or session chair and as speaker for a variety of DIA workshops in the US and Japan.

DIA's 'Outstanding Service Award' is given to recognize individuals who consistently, through their volunteer efforts, have made steady contributions to the DIA mission and vision, exceeding expectations. Dr Geary fulfils these requirements not just for DIA, but for Pharmaceutical Medicine as a whole – congratulations, Dr Geary.

In Brief

Stewart Geary grew up in Utah on the western edge of the Rocky Mountains, in the United States of America. He recalls the influence a high school chemistry teacher had in his early interest in medicine and pharmacology. "I enjoyed the advantage of having a terrific high school chemistry teacher, Paul Fore, who introduced me to the fascinating world of chemistry where you could both discover how nature works and apply science to the very human problems of sickness and disease. I was also influenced by reading *The Microbe Hunters*, the wonderful book by Paul de Kruif that describes the work of Koch and Pasteur and Ehrlich. I remember thinking how neat it would be to discover a new medicine that could change the world the way those early discoveries in microbiology have created a better world for us today."

In 1985 he graduated from Harvard College with a bachelor's degree in chemistry, then spent a year doing basic research on insulin-like growth factor receptors at Harvard Medical School before attending Stanford Medical School from which he earned an MD degree in 1990. He went on to complete a residency in urology at the Stanford University Medical Center in 1996.

His Character

When asked how he first got involved in pharmacovigilance Dr Geary said, "I had worked briefly in Clinical Development at Eisai Co., Ltd. for six months between graduation from medical school and starting a residency in urology, and I had expected to return to Clinical Development when I was invited back to the company after finishing residency, but Eisai had recently been involved in the withdrawal of an antiviral compound in the Japanese market and was concentrating on strengthening its clinical safety and pharmacovigilance operations, so I was assigned to what was then called, somewhat pessimistically, the 'ADE Department' ".

One unusual aspect of Dr Geary's career is that he has spent the last 11 years in Japan, working at Eisai's headquarters in Tokyo. He explains: "For me, Japan has been the ideal base from which to develop my career. Not only do I have the advantage of living in one of the most interesting cities in the world, but I am daily confronted with an environment where many assumptions differ from those I grew up with. Pharmaceutical development is necessarily a global enterprise today but we all tend to assume that the approach to pharmaceuticals in our home country is the most natural or logical one and that can cause friction as we implement multinational drug development programs. I want to help my colleagues understand that there is a variety of valid approaches to the issues we face in drug development and marketing, and that we need to meet the needs of each region as we bring new drugs to the market."

Since 1996, he has also worked off-and-on in Regulatory Affairs, but most of his time continues to be spent in the drug safety arena, both during Clinical Development and Post-Marketing. In fact, Dr Geary is Vice President and Global Safety Officer responsible for pharmacovigilance at Eisai Co., Ltd. in Tokyo, Japan. Needless to say, he speaks Japanese fluently.

But then, how does he coordinate all of these strands? Dr Geary: "The requirements and expectations for the safety of pharmaceuticals have significantly expanded during my career in the industry, and although there have been efforts toward global harmonization, in fact we see that each country has different expectations for how individual safety issues are handled. I believe the way to approach this is to have centralized, uniform scientific assessments of safety issues but to allow safety professionals in each country, working with their local regulatory authority, to interpret how that assessment is best applied in their local environment."

Dr Geary has published on the Japanese pharmaceutical industry and frequently lectures on global pharmaceutical regulations. "My colleagues in Japan expect me to explain the US and EU regulatory ▶ page 5

Dr Stewart Geary: "I sometimes get a chance to indulge my interest in scuba diving."

Personal Snapshot

◀ page 4 environment to them while those in the US or Europe look to me to explain the situation in Japan. I learn more from researching the answers to their questions than they suspect; if they realized how little I knew in advance of their questions they would probably look elsewhere for answers!" This assumption obviously is far from the truth.

With all those responsibilities at work and in industry associations, what does he do in his free time? "My favorite hours are those I spend with my wife Anna and our three boys, Nathan, Thatcher and Tiernan. I also sometimes get a chance to indulge my interest in scuba diving. There are many beautiful locations here in Asia for coral reef diving and our whole family enjoys a day at a tropical beach."

His Vision

"In Pharmaceutical Medicine we have the opportunity to help not just the patients we could physically see in a day at the clinic, but to change the practice of medicine and expand the treatment options for patients around the world. That is a tremendous privilege, but it likewise requires tremendous effort and teamwork from colleagues around the world. Much of clinical medicine is taught by example, practice and repetition and likewise in Pharmaceutical Medicine as we work together, we teach each other new techniques and approaches in solving the problems of drug safety and development. I have benefited greatly from the experiences and examples of senior colleagues in industry and I would like to share those lessons with the next generation of Pharmaceutical Medicine professionals."

Eckhard Boettcher-Buehler ■

Media Scope

PM – History, Global Status, Evolution

Those interested in the international evolution of Pharmaceutical Medicine should take note of a review entitled "Pharmaceutical Medicine – History, Global Status, Evolution and Development" recently published by Professor Peter D. Stonier, Dr Honorio Silva and Dr Herman Lahon (International Journal of Pharmaceutical Medicine 2007, Vol. 21, 4:253-262; available at www.fpm.org.uk members only). The Authors are well-respected experts in Pharmaceutical Medicine and have authoritatively influenced the profession. ■

Reports & Concepts

IFAPP at the 8th EACPT Conference

The Netherlands • The 8th Conference of the 'European Association for Clinical Pharmacology and Therapeutics' – EACPT 2007 – was held in Amsterdam, the Netherlands, from 29 August to 1 September 2007, attended by more than 850 delegates from 55 countries. IFAPP sponsored two symposia.

The first IFAPP symposium, entitled "Clinical research in the EU after the EU Directive", was attended by some 250 participants who showed great interest in the speakers' comments regarding the EU Directive on clinical trials.

Marcel Kenter, the Netherlands, reported data from a multicenter global study on diabetic neuropathy, initiated a few months after the EU Directive implementation. His experience was quite negative, with average protocol approval times in Europe of 85 days (Ethics Committee, EC, after the EU Directive) and 59 days (EC with local procedures); while in the US approval times were 45 days (local Institutional Review Boards – IRBs) and 15 days (central IRB).

Ernst Singer, Austria, highlighted the decline of academic research after the EU Directive, showing that in his hospital in Vienna the annual number of studies promoted by investigators decreased from 200 to only 50 during the period 2000-2006.

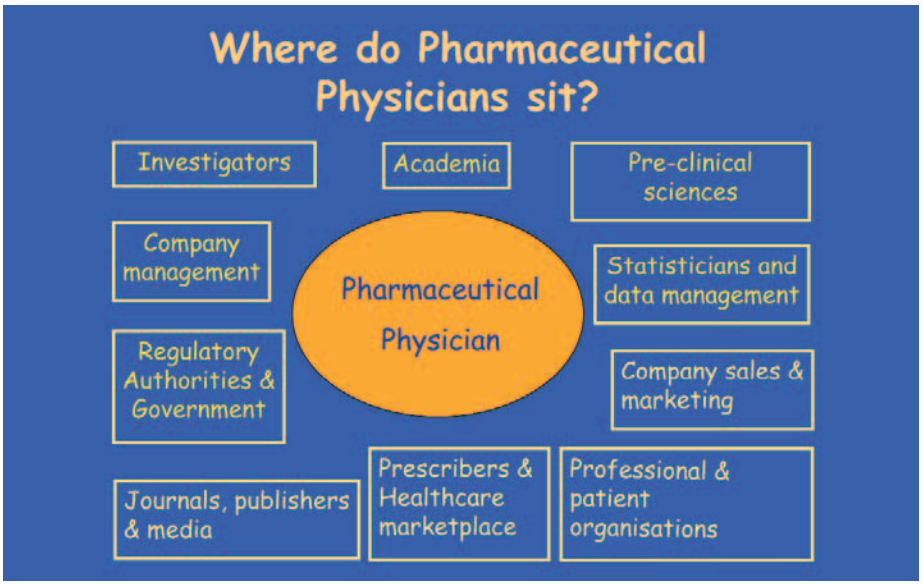
Heinz Carmann, Austria, provided a detailed overview of clinical trial opportunities emerging in new countries, not only in Eastern Europe, but also in China, India, and the Middle East. Francesco Pignatti, Italy, EMEA member, reported that regulators are following very carefully the evolution of the EU Directive implementation. He also discussed the opportunities to use new clinical trial designs like adaptive designs, which is indeed another tool to accelerate studies, as the required number of patients will be limited. Finally Willem R. Verweij, the Netherlands, member of the Dutch drug agency, reported on the role of inspectors not only to control, but also to educate clinical trial actors.

In conclusion, it was a lively symposium animated by several insightful questions from the audience, which gave IFAPP a good visibility.

IFAPP's second symposium on "Pharmaceutical Medicine: the Vision of IFAPP" was held during the early evening of the same day with some 50 participants. Susan Bews, United Kingdom, Adam Cohen, the Netherlands, Peter Stonier, United Kingdom, and Juan Lahuerta, Spain, illustrated – respectively – the key role of the 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom,' the interactions between Clinical Pharmacology and Pharmaceutical Medicine, the key role of the pharmaceutical physician, and finally the role of IFAPP's 'Council for Education in Pharmaceutical Medicine' (CEPM).

Rudolf van Olden, the Netherlands, and Domenico Criscuolo, Italy, who chaired both IFAPP symposia, commented that both events were of good value, were very well presented by all speakers and contributed to further improve the image of IFAPP among the scientific community.

Dr Domenico Criscuolo, Member of IFAPP's Executive Committee, Colleretto Giacosa, Italy ■



(adapted by Peter Stonier 2007)

IFAPP Interactive: Please Respond

Short Tutorial in Ethical Conduct Decision-Making

Ethics is not a test whether a decision is right or wrong, but about exploring the implications of making decisions.

The Ethical Decision Concept was introduced at IFAPP's Executive Committee face-to-face meeting in Vienna in March 2007, stimulating interest and discussion. Therefore IFAPP World would like to review these concepts to encourage further debate.

What Is Ethics?

A common philosophical definition considers ethics to be the "Science of Conduct," while others call it "Values Management." It is all about the fundamental ground rules by which we live our lives in the community, guided by common sense behavior.

There are two major challenges to note when talking about ethics in general and within Pharmaceutical Medicine particularly:

- There is a trend that "values," which previously were sacrosanct, are now being questioned.
- Assumptions and perspectives are being re-evaluated.

Furthermore, the decision process in Pharmaceutical Medicine has to acknowledge an international or global perspective.

Hence the ethical decision calls even more for a deliberation.

Principles of Biomedical Ethics

Four core principles of biomedical ethics were enunciated by Tom L. Beauchamp and James F. Childress in 1994 – revised and expanded upon by almost every important discussion of theory and principle in 2001: "Respect for Autonomy, Nonmaleficence, Beneficence, and Justice" [1].

These principles need to be considered when making an informed decision.

The Tutorial

The following scenario is a hypothetical exercise, based on various possible situations.

Scenario

1. Health area: Adolescence Pediatrics.
2. Investigational product: A new medication for oral contraception, which already is approved by the health authorities of some eminent countries and is about to be marketed there. The product is as yet not approved for women less than 18 years of age.
3. Clinical trial: It is a global clinical trial with participating centers in the US and Europe, in Asia and in Africa. Subjects are females aged 10 to 18.

4. Trial subject in question: An adolescent female aged 13 years with the assumption that she is sexually active. She is God-fearing. She is living with her mother, who is a practicing physician with expertise and research interest in oral contraception, also an investigator.
5. The investigator: Female physician with a broad expertise in oral contraception and clinical experience with adults and adolescents.

Dilemma 1:

The investigator is the mother of the adolescent female, who is a potential trial subject.

Dilemma 2:

The adolescent girl has requested contraception at a clinic without her mother's knowledge.

Questions

1. What are the implications – ethically and morally? (please comment briefly)
2. Are there any religious and global implications? (yes or no – why or why not)
3. Do you set up any additional assumptions? (please describe briefly)
4. Should the mother decide to put her young daughter in this clinical trial? (yes or no – why or why not)
5. Should the mother as a physician ask her young daughter whether she would be prepared and willing to participate in this clinical trial? (yes or no – why or why not)

Practical Guides and Business Models

There are several business models and practical guides available to exercise informed decision-making with ethical principles considerations.

As an instruction for the exercise above, and for simplicity, perhaps the Laura Nash model [2] with its 12 questions is one, which from an IFAPP World reader's perspective may be the most workable. It intends to make decision-making more practical, rather than relying on abstract philosophical concepts.

The Laura Nash Model

1. Have you defined the problem accurately? Gain precise facts and many of them.
2. How would you define the problem if you stood on the other side of the fence? Consider how others perceive it; are there alternatives?
3. How did this situation occur in the first place? Consider the history, problem or symptoms.
4. To whom and what do you give your loyalties as a person and as a member of the corporation? Private duty versus corporate policy or norms.
5. What is your intention in making this decision? Can you take pride in your action?
6. How does this intention compare with like results? Are results harmful even with good intentions?
7. Whom could your decision or action injure? A good thing resulting in a bad end? Want A, got B.
8. Can you engage the affected parties in a discussion of the problem before you make your decision? Example: talk to workers before closing the plant.
9. Are you confident that your position will be valid over a long period of time, as it seems now? Look at long-term consequences.
10. Could you disclose your decision or action without qualms to your boss, your CEO, the board of directors, your family or society as a whole? Would you feel comfortable with this on TV?
11. What is the symbolic potential of your action if understood? If misunderstood? Sincerity and the perception of others.
12. Under what conditions would you allow exception to your stand? Speeding to a hospital with a heart attack victim.

Please Respond

We kindly invite you to take a second close look at the scenario outlined above, and evaluate the assumptions. Then make an informed decision on how you would treat the adolescent female, or how you would proceed as her mother as a health professional. Utilize the Laura Nash model presented earlier. If necessary for your decision, you are welcome to set up additional assumptions at your discretion. Then address the questions posed above.

Please respond in an email to IFAPP World (ifapp@planet.nl) – subject "Ethical Conduct" – and provide your answers and brief comments, marked with

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IFAPP Interactive

◀ page 6 Q1, Q2, Q3, Q4 and Q5 – complete or incomplete, with or without your name. We are passionate about the international or global ethical perspective in making an informed decision with regard to this scenario. It is not at all a test whether the decision is right or wrong, but part of a thinking process to improve our decision-making skills. From your responses, we will create further exercises for ethical conduct decision-making.

Dr Sander Becker, Co-Chairperson of IFAPP's International Working Party on Ethics, Sydney, Australia, with specific involvement from Dr Jane Barrett, Member of IFAPP's Executive Committee (EC), Wokingham, Berkshire, United Kingdom, and IFAPP's EC. ■

References: *1. Beauchamp TL, Childress JF: "Principles of Biomedical Ethics", Fifth Edition, Oxford, New York 2001, Oxford University Press.*
2. Laura Nash: "Ethics without the sermon", Harvard Business Review 1981, 56/6:79-90.

IFAPP's Regional Update

New AMIFE President in Spain

Spain • In October 2007 the general assembly of the Spanish 'Society of Pharmaceutical Industry Physicians' (AMIFE – www.amife.org) elected a new board of directors that will lead the association for the next two years. New AMIFE President is Dr José Maria Giménez Arnau, Chief Scientific Officer at Novartis Pharma Spain, former AMIFE Vice-President and delegate to IFAPP. Dr Arturo Lopez-Gil, Head of Clinical Development at MSD, is AMIFE Vice-President (VP). Per recently renewed AMIFE statutes the VP will automatically become President in two years.

Sincere thanks were extended to AMIFE Past President, Dr Jorge Gonzalez-Esteban, Medical Director at MSD, for his excellent work for AMIFE and the Spanish Pharmaceutical Medicine. The board members showed their gratitude at a ceremonial dinner in Madrid right after the elections. ■

Dr José Maria Giménez Arnau, AMIFE President

Dr Arturo Lopez-Gil, AMIFE Vice-President

Reports & Concepts

DIA's 43rd Annual Meeting • First Part

Bioethics – a Global Challenge

Professor Gerfried Nell, Vienna, Austria, IFAPP President Elect

USA • Today most clinical drug development programs and clinical trials are global enterprises, only accomplished after bioethical evaluation. This calls for certain global standards to be implemented, which ethical evaluation has to follow. Therefore it is necessary, to provide essential education for members of Ethics Committees (ECs) and Institutional Review Boards (IRBs, US usage). This was a key session topic at the 43rd Annual Meeting of the 'Drug Information Association' (DIA) in June 2007 in Atlanta, Georgia, USA entitled "Global Challenges with Bioethics in IRB's Training."

The DIA session intended to draw an inventory of existing activities, measures and programs currently in place for education and training of EC and IRB members in the US, Europe and Latin America. Lastly a comparison of the identified activities, measures and programs was intended to provide an overview of further development needs.

As agreed by all invited speakers, a specific EC and IRB member educational program is mandatory. However, the activities, measures and programs for this education as well as legal regulations widely vary from region to region. However, there could hardly be a starker contrast between the huge monetary investments and personnel for education and training of clinical research professionals – investigators, Clinical Research Associates (CRAs), clinical trial coordinators – on one side and the marginal resources spent on EC and IRB member education on the other side.

USA: Selective Approaches, no Consistent Standards

Chaired by Dr Gustavo Kesselring, President of the 'Brazilian Society of Pharmaceutical Medicine' (SBMF), São Paulo, Brazil, the first speaker Dr Gary L Chadwick, University of Rochester, NY, USA, explained the US program in his talk entitled "What Is in Place, and Is It Enough?" For some years the 'Office of Human Research Protection' (OHRP) of the 'United States Department of Health and Human Services' (DHHS) has required the chairperson of an IRB to complete a training course – this was purely an insurance-related obligation. Currently there are no legal stipulations with regards to any IRB member education or training, but organizations as, e.g., the 'Association for the Accreditation of Human Research Protection Programs' (AAHRPP) attended to this task and called for adequate knowledge and skills of all, who are in charge for the safety and rights of patients in clinical research. According to AAHRPP, details have to be defined by the respective institution.

Atlanta, Georgia, USA

This lack of consistent regulations has caused huge differences in training requirements, training course formats and qualification of the respective trainers. The training commonly follows the basic requirements of the DHHS and the 'Food and Drug Administration' (FDA) and imparts knowledge of the "Belmont Reports" and ICH E-6 "Good Clinical Practice".

There are national courses, e.g., sponsored by the 'National Institutes of Health' (NHI) and several home-grown courses. Commonly the national courses are provided by the highest qualified authors with a focus on academic issues, while home-grown courses more likely address the specific needs of a respective institution. The level of training courses differs whether the training is for IRB chairpersons or ordinary IRB members; there also are courses for beginners and for advanced learners.

Overall, in the US several well-designed and well-organized approaches are available for continued education and training of IRB members. However, there is no consistent standard and structure currently in place.

The second part of the report with a focus on Europe and Latin America will be published in IFAPP World I/2008. ■

IFAPP's Regional Update

New Board of APPA

Australia • In September 2007 Dr Leanne Wall, Medical Director at Schering-Plough Australia, was elected as President of the 'Australian Pharmaceutical Physicians Association' (APPA). Dr Wall presides the APPA Executive Committee for 2007-2008 with positions as follows: Vice President Charmaine Gittleson, Secretary Guy Gavagna, Treasurer Malcolm Lawrie, Committee Rob Creek, Eugene Goh, Glen Pater, Peter Stewart, Linda Swan. Dr Wall replaced Dr Jeffrey Hassall. ■

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News from IFAPP's CEPM

Education in Pharmaceutical Medicine – an Update

When IFAPP created the 'Council for Education in Pharmaceutical Medicine' (CEPM) in 2001, it was given five major objectives:

1. To contribute to the harmonization of the existing Postgraduate Courses in Pharmaceutical Medicine (PGCPMs), to assist IFAPP's national member associations (nMAs) to establish appropriate educational and training programs in Pharmaceutical Medicine and to accredit those PGCPMs, which comply with the syllabus established by IFAPP.

2. To assist Universities to establish additional PGCPMs.

3. To support the development of structured Continuing Medical Education/Continuing Professional Development (CME/CPD) programs in Pharmaceutical Medicine by the nMAs.

4. To promote the mutual recognition of equivalent educational qualifications and CME/CPD requirements between countries.

5. To obtain the recognition of Pharmaceutical Medicine as a distinct medical specialty.

The CEPM counts 30 members who are those members of the nMAs interested in education and training. Most of them are participating in one or more of the six Working Groups (WGs) of the CEPM.

Activities

The activities of the CEPM can be summarized as follows:

Objective 1: Harmonization and Accreditation of PGCPMs

Between 2002 and 2007 CEPM has organized the visit and accreditation of 11 PGCPMs. Nine are located in European Universities (Barcelona, Basel, Belgrade, Brussels, Cardiff, Dublin, London-Surrey, Madrid and Stockholm), one in the University of Mexico and the most recent one is in Hibernia College of Dublin. This program is ongoing and further accreditations are expected in 2008.

Working Group I • The IFAPP syllabus for courses in PM is the benchmark on which the accreditation of PGCPMs is based. It is an essential tool in the process. WG I has the task to revise the syllabus when needed and to issue new up-to-date versions. The latest updated version is available on the IFAPP website www.ifapp.org in the section "education".

Objective 2: Assist in Establishing Additional PGCPMs

Since its foundation CEPM has assisted in the establishment of several Postgraduate Courses in Pharmaceutical Medicine. Further courses are being established or are currently in their first year such as at the Universities of Seoul, Budapest, California, Sydney, Buenos Aires, São Paulo, Singapore, Djakarta, and Teijin.

Working Group II • This WG was specifically created in order to assist in the establishment of the PGCPM at the University of Budapest. The idea is to create a course for the Central European Area in cooperation with other central European universities such as Vienna, Prague and Belgrade.

Working Group III • The objective of WG III is to produce an international computerized interactive training course for clinical investigators. This course was set up in cooperation with the University of Brussels and is now available under the name "E-Clin". It will be made available worldwide to the nMAs through the CEPM. The WG III remains responsible for the updating of the course on a yearly basis.

Objective 3: Assist in Establishing National CME/CPD Programs

Establishing CME/CPD programs for pharmaceutical physicians (PPs) is obviously a local responsibility and nMAs should give due diligence to this problem. The CEPM is prepared to assist wherever help is needed. In order to give some guidelines to the nMAs the CEPM set up WG IV.

Working Group IV • This WG wrote the "Guidance Notes for the Establishment of Continuing Medical Education/Continuing Professional Development programs in Pharmaceutical Medicine". These notes were circulated to all nMAs and are available on IFAPP's website.

Objective 4: Promote Mutual Recognition of Diplomas in PM

The objective is to obtain that the universities whose PGCPM was accredited by IFAPP mutually recognize the equivalence of the diplomas in Pharmaceutical Medicine they award to the students who passed successfully the examinations and/or assessments. This can only be obtained by bringing together the directors of the PGCPMs. As most of the accredited PGCPMs are located in Europe, the CEPM decided to organize a meeting of the directors of the 13 PGCPMs currently running in Europe. The meeting took place on 7 June 2007 in Brussels and was the foundation meeting of the "European Federation of Courses in Pharmaceutical Medicine (EFCPM)". A Steering Committee was elected, which met for the first time in Brussels on 16 August 2007. A similar meeting will be organized for the Asian region in 2008.

Objective 5: Promote the Recognition of PM as a New Medical Specialty

Considering that Europe is losing in competitiveness versus the US in terms of research and discovery of innovative medicines, the European Commission in cooperation with the 'European Federation of Pharmaceutical Industries and Associations' (EFPIA) is setting up an "Innovative Medicines Initiative" (IMI) and a "Strategic Research Agenda" (SRA). The objective is to improve the predictivity of efficacy and safety of new compounds, to improve knowledge management and to improve the training and education of the professionals involved in pharmaceutical R&D, regulatory affairs, pharmacovigilance, etc. The latter objective is of great interest to PPs as it specifically mentions the need to recognize Pharmaceutical Medicine as a new medical specialty. The project involves the creation of a 'European Medicines Research Academy' (EMRA) bringing together "centers of excellence" of each scientific discipline involved in R&D of new medicines. The objective of the CEPM is to obtain that the "center of excellence for Pharmaceutical Medicine" should be a tripartite body composed of the European Chapter of the CEPM, the 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom' and the recently founded EFCPM mentioned under Objective 4.

The CEPM counts two more WGs:

Working Group V • This WG is in charge of producing a multilingual glossary English versus several Eastern European languages of medical terms used in Pharmaceutical Medicine.

Working Group VI • This WG is in charge of communicating on the activities of the CEPM to IFAPP's Executive Committee, to the nMAs, to IFAPP World. This WG is also responsible for updating at regular intervals the section "education" on IFAPP's website and to provide pertinent information on the CEPM activities for inclusion in that section.

Dr Herman Lahon, IFAPP's Treasurer, Brussels, Belgium, and Professor Jean-Paul Deslypere, Member of IFAPP's Executive Committee, Chairman of CEPM, Singapore ■

Reports & Concepts

PM Training Proposal Passes First Filter of the European 'Innovative Medicines Initiative'

As reported earlier, IFAPP's European Chapter of the 'Council for Education in Pharmaceutical Medicine' (CEPM) held a meeting in June 2007 in Brussels, Belgium, with the directors of Postgraduate Courses in Pharmaceutical Medicine from major European universities. The participants agreed to form a group, which was tentatively designated as the 'European Federation of Courses of Pharmaceutical Medicine' (EFCPM), convened with the aim of agreeing a common proposal to meet the European 'Innovative Medicines Initiative' (IMI) call requirements for a joint project to foster Pharmaceutical Medicine in Europe in the coming years.

IMI, set up as a not-for-profit organization and run jointly by the European Commission and the 'European Federation of Pharmaceutical Industries and Associations' (EFPIA), provides an excellent opportunity to bring together all European parties involved in the education and training in Pharmaceutical Medicine. Based on IMI's 'Strategic Research Agenda' (SRA), the topics for the first IMI call have been proposed and agreed upon by the EFPIA Research Directors Group, representing a proportion of major pharmaceutical companies.

"Pharmaceutical Medicine Training Programme"

Among those projects reviewed and initially accepted is a six-page document entitled "Pharmaceutical Medicine Training Programme". The document has been prepared in summer 2007 by representatives of IFAPP, of the 'Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom' and the newly formed EFCPM. Thus, all important stakeholders have had a say into what should be addressed for future education and training of Pharmaceutical Medicine professionals in Europe.

The "Pharmaceutical Medicine Training Programme" establishes a number of actions to be rolled-out over a four-year period, defining current assets and future needs for the various stages of education and training. The vision is for a European network of existing and new academic centers working in harmony to deliver a common Pharmaceutical Medicine syllabus, under widely accepted training schemes, with advanced e-learning methods. This also might include training of investigators in Good Clinical Practice. A quality assessment of the whole process has to be ingrained right from the start.

The IMI process, as established, requires the constitution of pairs of consortia (groups of institutions committed to a particular project). The first consortium (EFPIA) is made up of pharmaceutical companies as members of EFPIA. The second consortium (public) should be composed "ad hoc" of academic bodies, small and medium sized enterprises, patient organizations, regulators, etc., that would work together with the EFPIA consortium to meet the proposal objectives. The consortia will be invited – likely at the beginning of 2008 – to submit pre-proposals outlining what they can offer to solve the issues raised in the calls. The received pre-proposals will then go through a peer-review selection process in order to combine those most suitable pairs of consortia. The opportunity of providing extensive and high-quality Pharmaceutical Medicine education and training throughout Europe seems closer to become a reality.

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

IFAPP News

www.ifapp.org Attracts More and More Visitors

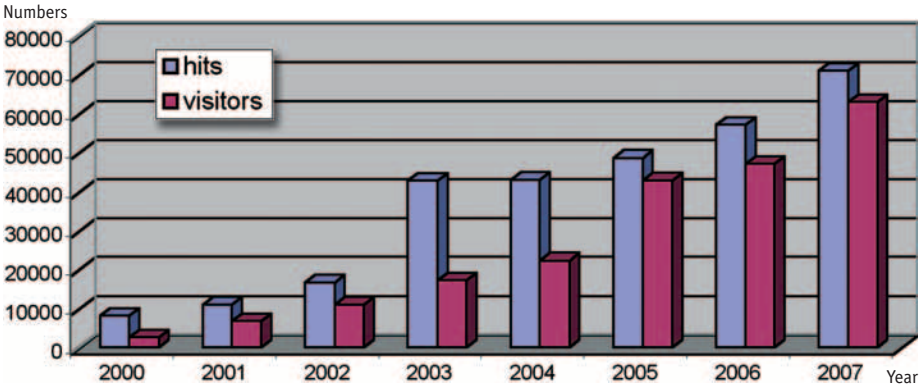
The number of visitors and hits on IFAPP's website has increased enormously in recent years and may reach a tenfold increase from January 2000 up to December 2007 (figure).

While there were 8,102 hits from 2,501 visitors counted for the year 2000, these figures have increased to 57,125 hits from 47,024 visitors during 2006. Between 1 January and 31 October 2007, the counter already showed 70,984 hits from 62,929 visitors and this is expected to increase further by year-end.

These figures clearly indicate a ramping interest in the information IFAPP provides on its website.

Stimulated by the high number of visitors, IFAPP currently is reviewing its presentation in the world-wide web with the objective to redevelop its website for even greater usability. The launch is planned for the first quarter of 2008. ■

Hits and visitors on www.ifapp.org year by year:



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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Reports & Concepts

4th Latin American Congress of Clinical Research • São Paulo, Brazil, in September 2007 • First Part

Global Initiatives of Clinical Research in Latin America

Dr Paulo Aligieri, São Paulo, Brazil

Brazil • "An exceptional congress" is how participants from academia and industry unanimously described the 4th 'Latin American Congress of Clinical Research' which ran from 27 to 29 September 2007. Jointly organized by the 'Sociedade Brasileira de Medicina Farmacêutica' (SBMF) and the 'Drug Information Association' (DIA) in São Paulo, Brazil, it had a record number of lecturers and speakers attending from IFAPP, DIA, the US-American Food and Drug Administration (FDA), and the European Medicines Agency (EMEA). Several dozen national and international exhibitors of all varieties participated.

Dr Gustavo Kesselring, SBMF President and Chairperson of the Congress, summarized: "The overall result of the congress is the constitution of a greater understanding regarding all clinical research facets of the participants who are professionals from academia, industry, administration and government."

IFAPP's Executive Committee Members: Prof Gerfried Nell, Austria, Dr Luis Collia, Argentina, Dr Johanna Schenk, Germany, and Dr Gustavo Kesselring, Brazil

Country Selection from Sponsor's Perspective

When choosing countries for multicenter study participation several factors should be considered. According to Dr Adri Pols, Vice President Global Clinical Monitoring Organon, the Netherlands, these include compliance with Good Clinical Practice standards, skills of professionals involved in clinical research, and trustworthy research ethics. Strategic aspects comprise the cost-benefit ratio, client preferences, local registration requirements, size of the domestic market and local marketing perspectives.

Other issues worth considering are: regulatory agency flexibility, research subject availability and centers of excellence with optimal performance, as well as company subsidiary presence. A reliable information exchange among all parties involved in the research is mandatory, especially when external personnel are involved.

Dr Adri Pols, the Netherlands, Dr Gysélle Tannous and Dr Laura Luchini, both Brazil, and Dr Victoria Vazquez, Mexico

Trials with Orphan Drugs

Orphan drug research and development was subject of a presentation by Dr Carlos Ruchaud, Medical Director, Genzyme, Brazil. In the US it is regulated by the 'Orphan Drug Act' (ODA), which became effective in January 1983 as a sub-clause of 'Food and Drug Administration' (FDA) regulations; orphan drug R&D is rewarded through tax reductions and marketing exclusivity for the specific drug over an extended time. Since 2000, a similar status exists in the European Union administered by the 'Committee for Orphan Medicinal Products' (COMP) of the 'European Medicines Agency' (EMEA).

In Brazil, orphan drug R&D faces many difficulties, since there is no adequate legislation. Protocol approvals and marketing authorizations are time consuming procedures. Also import licensures are complex. For example, even if the orphan drug is offered to the patient for free, the federal law imposes high taxes, which can easily exceed budgets. Overall, physicians, other health professionals as well as regulatory agents in Brazil need specific information and training in this area.

Dr Jorge Fiuza, Argentina, and Dr Carlos Ruchaud, Brazil

Currently the Brazilian regulatory agency is trying to solve these problems and ease protocol approval and importation challenges. They now allowed a limited drug reserve in Brazil in order for better treatment initiation soon after orphan disease diagnosis.

Pharmacogenomic Studies

Pharmacogenomics imposes several issues, as Dr David A Lepay, Senior Advisor for Clinical Science at the FDA Office of the Commissioner, USA, outlined in his talk. On ethical grounds, the subject protection concerns in this research area are generally not primarily subject safety, but rather subject rights. These are more "foreign" and less tangible to scientific and regulatory experts traditionally involved in designing, conducting, and evaluating clinical trials.

An exploratory sub-study should be approached and must be explained differently than a pivotal study involving validated (genomic) biomarkers. But even where the sub-study requires only one "extra vial" of blood, Good Clinical Practice standards affirm that subjects need to be informed and asked for their written consent. The credibility and acceptability of pharmacogenomic studies is tied to their ethical credibility and acceptability. The Independent Ethics Committee (IEC) membership must be equipped to understand and address pharmacogenomic studies, ensuring that adequate provision is made to protect the subjects' rights and welfare.

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Dr David A Lepay, USA

Reports & Concepts

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Experience in Site Inspection

Experience and results of research center inspections in Argentina were reported by Dr Anália C Perez, Argentina, member of the Argentinean 'Administración Nacional de Medicamentos, Alimentos y Tecnología Médica' (ANMAT). She described the legal basis and mandatory documents, the process steps, common findings and result synopsis. Voluntary action was agreed in 8% of a total of 374 inspections and official requirements were indicated in only 4%. In order to choose a research center for inspection, the Argentinean health authorities consider several factors, e.g., type of study protocol, rate of enrollment, number of SUSAR reports, etc. Perez underlined the importance of training and education to further improve research subject safety.

Professional Development and Career

Clinical research is an attractive field, regardless of where it is performed. It results in the development of new drugs, vaccines, devices, other procedures and other products that preserve or improve quality of life. In order to develop clinical research in Latin America, Dr Dennis Hurley, Mexico, Vice-President for Latin America with Kendle, said in his lecture "Professional Development and Career in Clinical Research", there are three questions which have to be answered: What do I like to do? What do I do well? Will this result in profit?

To ensure excellence in clinical research, a number of Brazilian and Latin American institutions offer professional support in this field. Furthermore, there are useful journals and websites focusing on this subject. Last but not least congresses, such as the 4th Latin American Congress of Clinical Research, are essential to broaden the clinical research understanding and expand the clinical research network. The opportunity to interact with more experienced colleagues is definitely a key factor in success.

The second part of the report will be published in IFAPP World I/2008 ■

Dr Geoff Gerard, USA, Dr Sergio Guerrero, USA, Dr Anália Perez, Argentina, and Dr Elie Fiss, Brazil

Dr Dennis Hurley, Mexico

Dates & Deadlines

13-17 January 2008 • Washington, DC, USA
DIA's 7th Annual Contemporary Pharmacovigilance & Risk Management Strategies Conference
Drug Information Association (DIA) • www.diahome.org

31 January – 1 February 2008 • Tokyo, Japan
DIA's 11th Annual Workshop for Clinical Data Management
Drug Information Association (DIA) • www.diahome.org

5-6 February 2008 • Johannesburg, South Africa
DIA's African Regulatory Conference: A Forum for Regulatory Authorities and the Pharmaceutical Industry
Drug Information Association (DIA) • www.diahome.org

3-5 March 2008 • Barcelona, Spain
DIA's 20th Annual EuroMeeting
Drug Information Association (DIA) • www.diahome.org

9-12 March 2008 • Orlando, Florida, USA
DIA's 19th Annual Workshop on Medical Communications
Drug Information Association (DIA) • www.diahome.org

17-18 March 2008 • Bangkok, Thailand
Pharmacogenetics and Drug Safety • Basic Concepts in Pharmacovigilance
International Society of Pharmacovigilance (ISOP)
www.isoponline.org

2-5 April 2008 • Orlando, Florida, USA
ASCPT's 9th Annual Meeting
American Society for Clinical Pharmacology and Therapeutics (ASCPT)
www.ascpt.org

25-29 April 2008 • Boston, Massachusetts, USA
ACRP 2008 Global Conference & Exhibition in Conjunction with the APPI Program for Pharmaceutical Physicians and Investigators
Association of Clinical Research Professionals (ACRP)
Academy of Pharmaceutical Physicians and Investigators (APPI)
www.acrpnet.org

26-28 April 2008 • Boston, Massachusetts, USA
ISPE Mid-Year Meeting
International Society for Pharmacoepidemiology (ISPE)
www.pharmacoepi.org

3-7 May 2008 • Toronto, Ontario, Canada
ISPOR 13th Annual International Meeting
International Society for Pharmacoeconomics and Outcome Research (ISPOR) • www.ispor.org

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

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IFAPP's Regional Update: Spain

Drug Safety: Particularities in Spain

Spain • Over the past few years, in the European Union important regulations regarding drug safety have been developed with mandated adoption by national regulatory authorities and pharmaceutical companies. This new legislative framework not only affected day-to-day pharmacovigilance operations, but also raised several specific procedural questions. To find appropriate answers, channel drug safety concerns and create fruitful regulatory authority relationships, the "Medical Association of the Spanish Pharmaceutical Industry" (AMIFE) set up a Pharmacovigilance Group (SEMIFE), which is open to all professionals interested in pharmacovigilance.

Initially SEMIFE established several teams working on important pharmacovigilance topics including signal detection, electronic transmission, report quality, pharmacovigilance inspections, and others. With work efficiency in mind, these groups were composed of a SEMIFE coordinator and pharmacovigilance specialists from any company that wished to participate. One team had been assigned the creation of a quarterly team activity bulletin; this bulletin was distributed via email to personnel in charge of pharmacovigilance within industry and government authorities in Spain.

Today, SEMIFE's mission has expanded to include training and SEMIFE's training courses, workshops and symposia are well established in creating a consistent approach to strengthen compliance with pharmacovigilance requirements. In all its activities, SEMIFE energetically involves representatives from the Spanish competent regulatory authorities in an attempt to foster awareness of the problems pharmaceutical companies face when turning regulations into practice.

'Good Pharmacovigilance Practice'

Spain has issued legally binding 'Good Pharmacovigilance Practice' regulations, effective for the pharmaceutical industry. Also a new Royal Decree for pharmacovigilance has just come into operation, which updates and expands Spanish pharmacovigilance regulations. Under these new rules, risk management activities are essential and pharmacoepidemiology, in particular observational post-authorization studies (PAS), are being emphasized as an essential tool of up-to-date pharmacovigilance in Spain.

In Spain since 2002, PAS have been rigorously regulated to prevent utilization as a drug marketing tool. In addition, requirements are not uniform since Spain has 17 autonomous regions and two autonomous cities, all of which have developed their own regulations. Therefore each individual PAS needs to be approved by the competent authorities of each participating autonomous region. However, in practice the implementation of observational studies is highly restricted by local authorities. As a consequence, the number of PAS conducted in Spain has declined dramatically since 2002, although their importance in investigating safety questions is beyond doubt.

Fortunately, the new Royal Decree for pharmacovigilance includes a centralized approval by the Spanish Drug Agency whenever a PAS is required by the competent authorities or when it is part of a Risk Management Plan. The Royal Decree also requires the Spanish Drug Agency to register all PAS; furthermore, any PAS fulfilling the definition of a post-authorization safety study needs to comply with the legal requirements of EudraLex Volume 9A.

Electronic ADR Reporting

Electronic reporting of Adverse Drug Reactions (ADRs) has also become an important issue. The Spanish authorities accept registration of foreign ADR reports to EudraVigilance, the central database of the 'European Medicines Agency' (EMEA). However, ADRs occurring in Spain must be reported to the Spanish Pharmacovigilance Database (FEDRA) with the additional requirement that narratives must be generated in both Spanish and English. There are two possibilities to comply with the Spanish requirements: online data entry into FEDRA for companies with a low number of reports, and XML transmission from the company database to FEDRA and vice versa, recommended for companies with products marketed outside the European Economic Area.

To date pharmaceutical companies have had to submit each ADR report to the pharmacovigilance center of the autonomous region where the ADR occurred as well as to the Spanish Drug Agency. However, in the new scenario, ADR reports need to be sent to one site only. Marketing Authorisation Holders (MAHs) are required to include the code of the National Institute of Statistics (INE) or the code of the autonomous region to facilitate the system forwarding the report to the corresponding site.

Spanish regulations also require the appointment of a permanent and continuously available Qualified Person responsible for pharmacovigilance (QPPV), who has legal obligations. The roles and responsibilities are similar to those included in EudraLex Volume 9A for the QPPV at European level, but in the new Royal Decree an additional responsibility has been added: that within Spain they must ensure that there are the necessary mechanisms to carry out regulatory actions adopted for safety reasons, as well as all those activities and studies included in the Risk Management Plan that are anticipated will be executed in Spain.

The Royal Decree recently published also requires that all materials to be distributed to healthcare professionals on new medicines must carry a pictograph (yellow triangle) for at least the first five years after marketing authorization.

Conclusion

Pharmacovigilance requires multifunctional groups that include experts from all areas: regulatory, academy and industry to share ideas and experiences. Thus, SEMIFE has become an authoritative voice in Spain. Its ultimate goal is to promote pharmacovigilance as a means to better protect public health.

SEMIFE Team: Dr C Barajas, Dr D Calderon, Dr T Cuchi, Dr P Diego, Dr I Rebollo, Dr C Rodríguez-Lopo, Spain ■

SEMIFE Coordinators of a Pharmacovigilance Symposium (Photo: C Barajas).